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*Sanofi US Services, Inc.*

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

ALISA LARSEN**,**

Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC ; SANOFI US SERVICES INC.

Defendants.

Case No. 3:23-cv-00782-YY

**NOTICE OF RELATED ACTIONS**

Pursuant to Local Rule 42-2 of the United States District Court for the District of Oregon, Defendant Sanofi US Services, Inc. ("Sanofi"), states that the above-captioned case is related to the following other case now pending in the District of Oregon:

1. *Marie Cavan v. Sanofi US Services, Inc.*, Case No. 6:23-cv-00768-AA, direct filed in the Eastern District of Louisiana and transferred to this District on May 24, 2023.

Each of these cases was directly filed in the Eastern District of Louisiana as part of the Taxotere (docetaxel) products liability multi-district litigation. *See* Transfer Order (Doc. 15836), *In re Taxotere (Docetaxel) Prod. Liab. Litig.*, No. 2:16-md-02740, Ex. A at 3, 6, 7, 8, 11 (E.D. La. May 15, 2023).[1] Each case is now transferred to this Court by Order of the MDL Court. *Id.*

Each case arises from events set forth in the Second Amended Master Long Form Complaint—the "operative pleading" in all cases. *See id.*, Ex. B at 3.[2] Each case involves the same defendant(s) in interest—Sanofi US Services, Inc. and/or sanofi-aventis U.S. LLC ("Sanofi"). Collectively, the cases would result in substantial duplication of labor if heard by different judges.

Accordingly, the cases should be designated as "Related Cases" under Local Rule 42-2.

Dated this 31st day of May, 2023.

LINDSAY HART, LLP

By: /s/ *Michael J. Estok*
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Attorneys for Defendant Sanofi US Services Inc.

[1] For the Court's convenience, a copy of the Transfer Order is attached.

[2] Each Plaintiff has also filed a Short Form Complaint consisting of approximately 14 paragraphs of information about their claims such as the specific docetaxel product(s) used and dates of administration. *See id.*, Ex. B at 4.

**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

| | | |
|---|---|---|
| **IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION** | ) | **MDL No. 16-2740** |
| | ) | **SECTION: "H" (5)** |
| **This document relates to all cases listed on attached Exhibit A.** | ) | |

**TRANSFER ORDER**

In accordance with 28 U.S.C. § 1404(a) and Pretrial Order No. 5, **IT IS ORDERED** that on **May 22, 2023** (hereinafter the "Transfer Date"), each of the above-captioned actions shall be **TRANSFERRED** to the United States District Courts identified on Exhibit A.

The Judicial Panel on Multidistrict Litigation has explained that "[o]nce common pretrial proceedings and any other pretrial proceedings that the transferee court considers appropriate have been completed in the transferee district," consolidated cases are ready for individual treatment.[1] When the Judicial Panel on Multidistrict Litigation created MDL 2740, it noted that "[c]entralizaion will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary."[2] As reflected in Case Management Order No. 39, attached as Exhibit B, this Court finds that the purposes behind consolidation have now been served. The Court has held two bellwether trials and has addressed numerous discovery disputes, dispositive motions, and other pretrial issues

[1] In re Air Crash Disaster Near Chicago, Ill., on May 25, 1979, 476 F. Supp. 445, 449 (J.P.M.L. 1979); In re Evergreen Valley Project Litig., 435 F. Supp. 923, 924 (J.P.M.L. 1977) ("It is not contemplated that a Section 1407 transferee judge will necessarily complete all pretrial proceedings in all actions transferred and assigned to him by the Panel, but rather that the transferee judge in his discretion will conduct the common pretrial proceedings with respect to the actions and any additional pretrial proceedings as he deems otherwise appropriate.").
[2] In re Taxotere (Docetaxel) Prod. Liab. Litig., MDL 2740, 220 F. Supp. 1360, 1361 (J.P.M.L. 2016).

involving factual and legal questions common to all cases in this MDL proceeding.[3] No further pretrial motions are pending in these cases, and transfer to the appropriate district courts appears to serve the interests of judicial efficiency.

The 81 cases identified in Exhibit A were directly filed within MDL 2740 in accordance with Pretrial Order No. 5.[4] As such, these cases may be transferred by this Court, pursuant to 28 U.S.C. § 1404, "to any other district or division where it might have been brought or to any district or division to which all parties have consented."[5]

Accordingly, upon the timely filing of any joint designations of the MDL 2740 record by counsel in the individual case, as outlined below, **IT IS ORDERED** that on **May 22, 2023** (ten days after the entry of this order) (hereinafter the "Transfer Date"), each of the above-captioned actions shall be **TRANSFERRED** to the United States District Courts identified on Exhibit A.

**IT IS FURTHER ORDERED** that from this date, May 12, 2023, through **May 22, 2023**, the parties shall confer and file in each individual member case all documents from the main MDL 2740 docket that the parties jointly deem relevant to constitute an appropriate record for the receiving court. When filing the documents from the main MDL, the parties are directed to utilize the CM/ECF event entitled "**DESIGNATION OF RECORD FOR MDL TRANSFERS**" (available under Civil > MDL TRANSFER > DESIGNATION OF RECORD FOR MDL TRANSFERS). Counsel may use this

[3] *See* Case Management Order No. 39 (outlining the proceedings that have occurred in the MDL since its 2016 inception and summarizing this Court's pretrial rulings applicable to all MDL cases).
[4] Rec. Doc. 131 (PTO 5).
[5] 28 U.S.C. § 1404. For purposes of remand or transfer, the transferor court was the presumed venue identified in Paragraph 8 of each Plaintiff's short form complaint. *Id*. On January 20, 2023, Sanofi filed its objections to 15 Plaintiffs' cases, alleging the Plaintiff had not identified the appropriate venue. Rec. Doc. 15412 (Defs.' Objs. to Venue under CMO 33).

event to upload their documents into each individual member case. Counsel are instructed to upload each document as separate pdfs in one docket entry. All cases that are pending on the Transfer Date shall be transferred, and the parties shall bear the consequences in the receiving court of any failure to prepare an appropriate record as directed in this Order.

**IT IS FURTHER ORDERED** that this Court retains jurisdiction to consider the fair and equitable assessment of any potential recovery for the services performed and expenses incurred by attorneys acting for administration and common benefit of all MDL plaintiffs.

**IT IS FINALLY ORDERED** that this Order **SUPERSEDES** the Suggestion of Remand previously entered by this Court on April 3, 2023 (Doc. 15763).

New Orleans, Louisiana, this 12th day of May, 2023.

**JANE TRICHE MILAZZO**
**UNITED STATES DISTRICT JUDGE**

# EXHIBIT A

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Alamil, Maria C | 2:18-cv-05166 | Direct File | Central District of California | Kagan Legal Group (now represented by Bachus & Schanker, LLC) | YES | YES | YES | YES |
| Ali, Aysha | 2:17-cv-14632 | Direct File | Northern District of California | Bachus & Schanker, LLC | YES | YES | N/A | N/A |
| Allain, Carol | 2:18-cv-01308 | Direct File | Middle District of Florida | Bachus & Schanker, LLC | YES | YES | YES | N/A |
| Armond, Helen | 2:18-cv-7009 | Direct File | Northern District of Georgia | TorHoerman Law LLC | YES | YES | N/A | NO |
| Ayers, Kathy | 2:17-cv-12947 | Direct File | Western District of Washington | Gomez Trial Attorneys | YES | YES | YES | NO |
| Ayers, Linda | 2:20-cv-00186 | Direct File | Northern District of Georgia | Scott Vicknair LLC | YES | YES | NO | N/A |
| Bales, Donna M | 2:18-cv-03855 | Direct File | Eastern District of Washington | Pendley, Baudin & Coffin, L.L.P. | YES | DECEASED | YES | N/A |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Bias, Tuwana T | 2:18-cv-12105 | Direct File | Western District of North Carolina | Johnson Becker | YES | YES | YES | N/A |
| Bogan, Alayna | 2:18-cv-10815 | Direct File | District of Nebraska | Reyes Brown Reilley | YES | YES | YES | N/A |
| Brazill, Sharon | 2:17-cv-10126 | Direct File | Northern District of Illinois | Pendley, Baudin & Coffin, L.L.P. | YES | NO | YES | NO |
| Brouillard, Edith P. | 2:20-cv-1086 | Direct File | Eastern District of Missouri | Brown & Crouppen | YES | YES | NO | N/A |
| Bumgarner, Charlotte | 2:18-cv-00685 | Direct File | Middle District of Florida | Bachus & Schanker, LLC | YES | YES | YES | NO |
| Cary, Gladys | 2:19-cv-12934 | Direct File | District of Nebraska | Reyes Brown Reilley | YES | YES | NO | NO |
| Cavan, Marie E | 2:17-cv-17209 | Direct File | District of Oregon | Fears Nachawati | YES | YES | YES | N/A |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Champaneri, Anuka | 2:18-cv-12979 | Direct File | District of South Carolina | Carey Danis & Lowe | YES | NO | NO | N/A |
| Conway, Ashley | 2:19-cv-09309 | Direct File | District of Maryland | Napoli Shkolnik PLLC | YES | YES | YES | NO |
| Cuaron, Maria | 2:20-cv-01945 | Direct File | Central District of California | Laborde Earles (now represented by Martzell, Bickford & Centola) | YES | YES | NO | NO |
| Cummings, Mathilda | 2:17-cv-07915 | Direct File | District of South Carolina | Pendley, Baudin & Coffin, L.L.P. | YES | YES | YES | N/A |
| Daniel, Margo | 2:17-cv-13082 | Direct File | District of New Jersey | Davis & Crump, P.C. | YES | YES | NO | NO |
| Davis, Cary | 2:18-cv-13336 | Direct File | Western District of North Carolina | Fears Nachawati | YES | YES | YES | NO |
| Davis, Regina A | 2:19-cv-09299 | Direct File | District of Maryland | Napoli Shkolnik PLLC | YES | YES | NO | NO |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Devens, Laura | 2:16-cv-17344 | Direct File | Southern District of New York | Whitfield Bryson LLP | YES | YES | N/A | Sanofi: NO Plaintiff: YES |
| Ditto, Lois Y | 2:17-cv-09040 | Direct File | District of Colorado | Pendley, Baudin & Coffin, L.L.P. | YES | NO | YES | NO |
| Dorman, Brenda | 2:17-cv-11505 | Direct File | Southern District of Indiana | Pittman, Dutton & Hellums, P.C. | YES | YES | YES | N/A |
| Douglas, Lynne A | 2:17-cv-17461 | Direct File | District of Massachusetts | Fears Nachawati | YES | YES | N/A | N/A |
| Furbeck, Lisa | 2:17-cv-08136 | Direct File | District of Delaware | Bachus & Schanker, LLC | YES | YES | NO | N/A |
| Fussell, Cinda | 2:18-cv-02928 | Direct File | Western District of North Carolina | Bachus & Schanker, LLC | YES | NO | YES | N/A |
| Gonzales, Martha | 2:17-cv-14125 | Direct File | District of Kansas | Brent Coon & Associates | YES | YES | NO | YES |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Green, Alma | 2:18-cv-3325 | Direct File | Middle District of Tennessee | Hissey, Mulderig & Friend, PLLC | YES | NO | NO | N/A |
| Hall, Margaret | 2:19-cv-12903 | Direct File | Middle District of Florida | Davis & Crump, P.C. | YES | YES | YES | N/A |
| Hammond, Tracy M | 2:17-cv-15446 | Direct File | Southern District of Indiana | Williams Hart Boundas Easterby, LLP | YES | YES | NO | N/A |
| Hanson, Holly | 2:17-cv-17938 | Direct File | District of Minnesota | McGartland Law Firm, PLLC | YES | YES | YES | YES |
| Harris, Vivian | 2:19-cv-02466 | Direct File | Eastern District of Pennsylvania | Bachus & Schanker, LLC | YES | NO | YES | N/A |
| Hines, Patricia A | 2:17-cv-06823 | Direct File | Central District of California | Pendley, Baudin & Coffin, L.L.P. | YES | NO | YES | YES |
| Hodges, Joyce | 2:18-cv-02632 | Direct File | Central District of Illinois | Bachus & Schanker, LLC | YES | NO | YES | N/A |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Horst, Peggy | 2:18-cv-13400 | Direct File | District of Maryland | Fears Nachawati | YES | YES | YES | N/A |
| House, Cheryl L | 2:17-cv-9149 | Direct File | Eastern District of Virginia | Lowe Law Group (now represented by Bachus & Schanker, LLC) | YES | NO | YES | NO |
| Hudson, Bonnie | 2:17-cv-14588 | Direct File | Middle District of North Carolina | Law Offices of A. Craig Eiland | YES | YES | YES | N/A |
| Jackson, Sylvia | 2:18-cv-04672 | Direct File | Middle District of Tennessee | Johnson Law Group | YES | YES | NO | N/A |
| Johnson, Angela | 2:17-cv-12160 | Direct File | Eastern District of Arkansas | Cory Watson | YES | YES | YES | NO |
| Johnson, Latasha S | 2:18-cv-9399 | Direct File | Middle District of North Carolina | Niemeyer, Grebel & Kruse | YES | NO | N/A | NO |
| Jones, Myra E | 2:17-cv-09545 | Direct File | District of Delaware | Bachus & Schanker, LLC | YES | YES | SET April 17, 2023 | N/A |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Jones, Regina A | 2:17-cv-12912 | Direct File | Middle District of Georgia | Hillard Martinez Gonzales LLP (now represented by Bachus & Schanker, LLC) | YES | YES | YES | N/A |
| Kaden, Kaila M | 2:17-cv-12755 | Direct File | Central District of California | Niemeyer, Grebel & Kruse | YES | NO | NO | N/A |
| Knox, Dulce | 2:20-cv-02303 | Direct File | District of Maryland | Fears Nachawati | YES | YES | YES | Sanofi: NO Plaintiff: YES |
| Lambert, Tresila | 2:18-cv-1219 | Direct File | Western District of Virginia | Bachus & Schanker, LLC | YES | YES | NO | N/A |
| Larsen, Alisa | 2:17-cv-14876 | Direct File | District of Oregon | Bachus & Schanker, LLC | YES | NO | NO | N/A |
| Maxwell, Reponza | 2:17-cv-12717 | Direct File | Northern District of Alabama | Wendt Law Firm, P.C. | YES | YES | NO | N/A |
| McClaflin, Gina | 2:17-cv-16980 | Direct File | District of Colorado | Bachus & Schanker, LLC | YES | YES | YES | N/A |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| McElrath, Myra J | 2:17-cv-12463 | Direct File | Northern District of Florida | Pendley, Baudin & Coffin, L.L.P. | YES | NO | YES | N/A |
| Moreland, Tabatha | 2:17-cv-07652 | Direct File | District of Delaware | Bachus & Schanker, LLC | YES | YES | SET April 21, 2023 | N/A |
| Necastro, Margaret | 2:17-cv-13940 | Direct File | Western District of Pennsylvania | Allen & Nolte, PLLC | YES | YES | NO | N/A |
| Newcomb, Deborah A | 2:17-cv-08799 | Direct File | Northern District of Ohio | Pendley, Baudin & Coffin, L.L.P. | YES | NO | YES | N/A |
| Niddrie, Suzanne | 2:18-cv-12080 | Direct File | District of Massachusetts | McSweeny/Langevin LLC | YES | YES | NO | NO |
| Ogilvie, Sharen | 2:18-cv-11635 | Direct File | Western District of Washington | Reyes Browne Reilley | YES | YES | YES | N/A |
| Pegues, Fanita | 2:18-cv-09026 | Direct File | District of Maryland | Cory Watson | YES | SET April 12, 2023 | YES | NO |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Pichler, Margaret | 2:17-cv-17457 | Direct File | Eastern District of Pennsylvania | Shaw Cowart, LLP | YES | YES | YES | N/A |
| Pickett, Sharon | 2:17-cv-11656 | Direct File | Eastern District of Arkansas | Cory Watson | YES | SET April 4, 2023 | YES | N/A |
| Primacio, Betsy | 2:17-cv-14016 | Direct File | Middle District of Florida | Gomez Trial Attorneys | YES | YES | YES | NO |
| Provencher, Elizabeth | 2:18-cv-10992 | Direct File | District of Maine | Reyes Browne Reilley | YES | NO | NO | N/A |
| Ragan, Kymberly | 2:17-cv-11081 | Direct File | Western District of Tennessee | Johnson Law Group | YES | YES | NO | N/A |
| Reevers, Mae | 2:19-cv-12268 | Direct File | District of Massachusetts | Roberts & Roberts (now represented by Fears Nachawati) | YES | YES | YES | N/A |
| Rouse, Fonda | 2:18-cv-10489 | Direct File | Middle District of North Carolina | Reyes Browne Reilley | YES | YES | N/A | N/A |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Schaff, Ellen | 2:18-cv-12576 | Direct File | Western District of Washington | Atkins & Markoff | YES | YES | NO | N/A |
| Sheppard, Jackie | 2:17-cv-11947 | Direct File | Southern District of Georgia | Allen & Nolte, PLLC | YES | YES | NO | N/A |
| Smith, Debra | 2:17-cv-11433 | Direct File | District of New Jersey | Bachus & Schanker, LLC | YES | YES | YES | N/A |
| Smith, Janet J | 2:17-cv-02728 | Direct File | Western District of Kentucky | Bachus & Schanker, LLC | YES | NO | YES | N/A |
| Smith, Linda | 2:19-cv-11856 | Direct File | District of Minnesota | McSweeney/Langevin LLC | YES | YES | NO | N/A |
| Smith, Sandra | 2:19-cv-12350 | Direct File | Southern District of Florida | Reyes Browne Reilley | YES | NO | NO | N/A |
| Stephens, Linda | 2:17-cv-15100 | Direct File | Western District of Tennessee | Carey Danis & Lowe | YES | YES | NO | N/A |
| Taylor, Sandra F. | 2:17-cv-13973 | Direct File | Eastern District of North Carolina | Zoll & Krantz, LLC | YES | YES | NO | NO |
| Thomas, Sylvia | 2:17-cv-13635 | Direct File | Central District of California | Gomez Trial Attorneys | YES | YES | YES | YES |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Tibbitts, Kimberly | 2:17-cv-10597 | Direct File | District of Delaware | Bachus & Schanker, LLC | YES | YES | YES | NO |
| Tomlinson, Sarah | 2:18-cv-00704 | Direct File | Middle District of Florida | Bachus & Schanker, LLC | YES | YES | YES | N/A |
| Utter, Mary K | 2:17-cv-14052 | Direct File | District of Kansas | Maher Law Firm | YES | YES | NO | NO |
| Vinson, Odessa | 2:17-cv-13555 | Direct File | District of Maryland | Whitfield Bryson LLP | YES | YES | YES | N/A |
| Warren Wiggins, Gloria | 2:17-cv-16751 | Direct File | Eastern District of Virginia | Meyers & Flowers, LLC | YES | YES | YES | N/A |
| Wrath, Maria | 2:17-cv-16503 | Direct File | Northern District of Ohio | Carey Danis & Lowe | YES | YES | NO | NO |
| Wearing, Alleshia | 2:18-cv-13835 | Direct File | Western District of New York | Fears Nachawati | YES | YES | YES | YES |

| Plaintiff | Case No. | Direct File or JPML Transfer | SFC Venue / Jurisdiction | Law Firm | Plaintiff Depo | Prescriber Depo | Sales Rep Depo | Treater Depo |
|---|---|---|---|---|---|---|---|---|
| Wolfe, Jody | 2:17-cv-15844 | Direct File | Western District of Pennsylvania | Bachus & Schanker, LLC | YES | NO | NO | NO |
| Yantzer, Carmen | 2:20-cv-03240 | Direct File | Northern District of North Dakota | Cutter Law PC | YES | NO | NO | NO |

# EXHIBIT B

**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

| | | |
|---|---|---|
| **IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION** | ) | **MDL No. 16-2740** |
| | ) | **SECTION: "H" (5)** |
| **This document relates to all cases.** | ) | |

**CASE MANAGEMENT ORDER NO. 39**
**(SUMMARY OF MDL 2740 PROCEEDINGS UPON SUGGESTION OF REMAND OR TRANSFER)**

On October 4, 2016, the Judicial Panel on Multidistrict Litigation ("JPML") transferred 28 civil actions to this Court for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.[1] The JPML concluded that these actions all shared common factual questions, including whether Taxotere (docetaxel), a chemotherapy drug, causes permanent hair loss, whether defendants were aware of this possible side effect, and whether they failed to warn patients.[2] Since that time, more than 15,000 lawsuits have been filed in the MDL, and 10,734 cases are currently pending in this Court.[3]

Plaintiffs in this MDL are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[4] that Plaintiffs were administered for the treatment of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi"). Plaintiffs allege that the drug caused permanent

[1] *See* In re Taxotere (Docetaxel) Prod. Liab. Litig., MDL 2740, 2016 WL 5845996 (U.S. Jud. Pan. Mult. Lit. Oct. 4, 2016).
[2] *Id.*
[3] U.S. JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, MDL STATISTICS REPORT – DISTRIBUTION OF PENDING MDL DOCKETS BY DISTRICT 2 (Feb. 16, 2023), https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-February-16-2023.pdf.
[4] Docetaxel is the generic version of Taxotere, though the Court uses the term "generic" loosely.

chemotherapy induced alopecia ("PCIA"). Plaintiffs assert several claims, including failure to warn, negligence, negligent misrepresentation, fraudulent misrepresentation, and fraudulent concealment.

As the transferee court, the Eastern District of Louisiana maintains on its website a summary of actions taken in this docket.[5] The JPML docket number is MDL-2740, and this Court's docket number is 2:16-md-02740-JTM-MBN. This Order outlines the proceedings that have occurred in the MDL since its 2016 inception and summarizes the Court's pretrial rulings applicable to all MDL cases. The purpose of this Order is to assist trial judges in transferor courts who may preside over the remaining discovery and trial of an individual Taxotere case. A copy of this Order will be provided to the transferor court upon transfer or remand, along with MDL filings relevant to the remanded case.

## I. THE MDL PROCEEDINGS

A summary of the MDL proceedings is provided below to assist courts on remand, if ordered by the JPML, and courts receiving transfers under 28 U.S.C. § 1404(a).

### A. Master Complaint and Short Form Complaint

Pretrial Order No. 15, entered February 10, 2017, set forth the deadlines for the filing of master and short form complaints, motions to dismiss, and master answers.[6] Plaintiffs filed a Master Complaint on March 31, 2017.[7] Plaintiffs then filed a First Amended Master Complaint to name certain Defendants correctly.[8] Defendants moved to dismiss the Master Complaint, which this Court granted in part. The Court dismissed Plaintiffs' claims for

[5] *See* https://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere.
[6] Rec. Doc. 230 (Pretrial Order "PTO" 15).
[7] Rec. Doc. 312 (Master Long Form Compl. & Demand for Jury Trial).
[8] Rec. Doc. 689 (First Am. Master Long Form Compl. & Demand for Jury Trial).

strict product liability for misrepresentation (Count II) and breach of express warranty (Count VIII) from the First Amended Master Complaint.[9] Plaintiffs then filed a Second Amended Master Complaint on September 27, 2018.[10]

The Second Amended Master Complaint remains the operative pleading. It asserts the following state-law claims: failure to warn (Count I); negligence (Count III); negligent misrepresentation (Count IV); fraudulent misrepresentation (Count V); fraudulent concealment (Count VI); and fraud and deceit (Count VII).[11] Plaintiffs seek both compensatory and punitive damages.[12] Plaintiff-specific allegations are contained in individual short form complaints,[13] and this Court has ruled that any fraud-based claims must be "perfected within the short form complaints filed in the individual member cases."[14] This Court has also required the parties to submit Plaintiff and Defendant Fact Sheets.[15]

The Court denied Plaintiffs' Motion for Leave to File Plaintiffs' Third Amended Master Long-Form Complaint on December 12, 2019.[16] Plaintiffs had sought to amend the Master Complaint to no longer define PCIA as manifesting six months after chemotherapy.[17] Plaintiffs' proposed amendment alleged that there is "no single definition" for PCIA, and therefore the amount of time to establish permanent hair loss varies from patient to patient.[18] In denying Plaintiffs' motion, this Court explained that "the main reason

[9] Rec. Doc. 877 (PTO 61).
[10] Rec. Doc. 4407.
[11] *Id.* ¶¶ 221–31, 240–311.
[12] *Id.* ¶ 320.
[13] Rec. Doc. 1463 (PTO 73).
[14] *See* Hr'g Tr. at 23:4–7 (Aug. 30, 2017) (Engelhardt, J., presiding).
[15] *See* Rec. Docs. 236 (PTO 18); 326 (PTO 38); 688 (PTO 55).
[16] *See* Rec. Doc. 8702 (Order & Reasons Denying Pls.' Mot. for Leave to File Pls.' Third Am. Master Long-Form Compl. & Jury Demand).
[17] *See id.* at 2.
[18] *See id.*

Plaintiffs wish to amend the Long-Form Complaint at this juncture is to save cases that are otherwise subject to dismissal for being filed too late."[19] All deadlines for Plaintiffs to amend their individual complaints without leave of court have passed.[20]

The parties were encouraged to stipulate to direct filing and streamlined service procedures in order to expedite the process of filing and service of Short Form Complaints and avoid the costs and delays associated with removal and transfer procedures and to streamline service, which was done. The Court entered a direct filing procedure[21] and streamlined service orders.[22] Recently, the Court entered Case Management Order No. 35 (Doc. 14456) on July 26, 2022, setting a deadline of August 31, 2022 to effect service of process on all Defendants named in Plaintiffs' respective Short Form Complaints.

**B. Personal Jurisdiction Over Foreign Sanofi Entities**

Because two of the four Sanofi entities sued by Plaintiffs in this MDL were foreign entities based in France, the PSC sought discovery relating to personal jurisdiction over these entities and the Sanofi defendants sought dismissal of claims for lack of jurisdiction. The parties filed a "Stipulation of Terms Related to Defendants, Sanofi and Aventis Pharma S.A."[23] Pursuant to the parties' stipulation, the Court dismissed Sanofi S.A. and Aventis Pharma S.A. ("French Defendants") without prejudice.[24] Thus, whether these French Defendants may be subject to a U.S. district court's jurisdiction remains a question that might require adjudication on remand should an individual Plaintiff seek to reinstate claims against the Sanofi French Defendant entities.

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[19] *See id.* at 4.
[20] Rec. Doc. 10338 (PTO 105).
[21] See Pretrial Order Nos. 4 and 5 (Docs. 122, 131).
[22] See Pretrial Order Nos. 9, 29/29A, 30, 32/32A, 33, 39/39A, 40/40A, 83 (Docs. 160, 303, 13877, 304, 307, 710, 308, 327, 711, 328, 509, 4263).
[23] Rec. Doc. 1072.
[24] Rec. Doc. 1462 (PTO 72).

### C. Case Management and Pretrial Orders

The primary orders governing pretrial management of this MDL are a series of case management orders ("CMO") and pretrial orders ("PTO"), along with certain amendments. To date, this Court has issued 63 CMOs and 150 PTOs. These orders are discussed throughout this Order and can be found on the MDL docket or this Court's website at https://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere.

### D. Lead and Liaison Counsel

On December 28, 2016, the Court appointed Plaintiffs' Co-Lead Counsel and Plaintiffs' Executive Committee.[25] Mr. Christopher Coffin of Pendley, Baudin & Coffin LLP, in New Orleans, Louisiana, and Ms. Karen Barth Menzies of Gibbs Law Group LLP, in El Segundo, California, are Co-Lead Counsel for Plaintiffs.[26] Mr. J. Kyle Bachus of Bachus & Schanker, LLC, in Denver, Colorado, and Mr. David Miceli of Milberg Coleman Bryson Phillips Grossman, in Carrollton, Georgia, serve on the Plaintiffs' Executive Committee with Mr. Coffin and Ms. Menzies.[27] The Court appointed the Plaintiffs' Executive Committee to coordinate and manage the responsibilities of the Plaintiffs' Steering Committee ("PSC"), schedule PSC meetings, and perform any other duties ordered by the Court.[28]

The Court has also appointed Liaison Counsel.[29] Ms. Dawn Barrios of Barrios, Kingsdorf & Casteix, LLP, in New Orleans, Louisiana, and Mr. M. Palmer Lambert of Pendley, Baudin & Coffin LLP, in New Orleans, Louisiana, are Plaintiffs' Liaison Counsel.[30] Mr. Douglas Moore of Irwin Fritchie

[25] Rec. Doc. 154 (Order Establishing Leadership Structure Within the PSC).
[26] *Id.* at 1.
[27] *Id.* The Court also appointed Ms. Dawn Barrios and Mr. M. Palmer Lambert as *ex-officio* members of the Plaintiffs' Executive Committee. *Id.* at 2.
[28] *Id.* at 1–2.
[29] Rec. Doc. 104 (PTO 2).
[30] *Id.* at 1.

Urquhart & Moore LLC, and John Olinde of Chaffe McCall, LLP, in New Orleans, Louisiana, are Defendants' Liaison Counsel.[31] Lead counsel for Sanofi are Jon A. Strongman, Harley V. Ratliff, and Adrienne L. Byard of Shook, Hardy & Bacon, LLP, in Kansas City, Missouri.[32]

**E. Plaintiffs' Steering Committee and Common Benefit Fund**

PTO 1 directed the selection and appointment of a PSC to conduct and coordinate the discovery stage of this litigation with Defendants.[33] The Court appointed members to the PSC on November 17, 2016.[34] The configuration of the PSC has changed during the course of the ligation,[35] as has the Court's Common Benefit Order. In February 2017, the Court entered PTO 19, which adopted the proposed Common Benefit Order submitted by Liaison Counsel and the PSC.[36] PTO 19 included an 8% holdback assessment—6% for attorneys' fees and 2% for expenses—stemming from "any and all amounts paid by defendants through settlement or pursuant to a judgment."[37] In September 2022, the Court granted the PSC's Motion to Modify PTO 19.[38] The Court increased the holdback for common benefit attorney's fees from 6% on the Gross Monetary Recovery to 15% on the Gross Monetary Recovery.[39] The Court also increased the holdback for common benefit costs from 2% on the Gross Monetary Recovery to 4.75% on the Gross Monetary Recovery.[40] The

[31] *Id.* at 2.
[32] Contact information for the 505(b)(2) Defendants' lead counsel is available on the Court's website. *See Contacts for MDL 2740 Taxotere (Docetaxel) Products Liability Litigation*, U.S. DIST. COURT, EASTERN DIST. OF LA., https://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere-contacts.
[33] Rec. Doc. 4 (PTO 1).
[34] Rec. Doc. 104.
[35] Rec. Doc. 11412 (PTO 110).
[36] Rec. Doc. 262 (PTO 19).
[37] *Id.* at 24–25.
[38] Rec. Doc. 15143 (Order Granting PSC's Mot. to Modify PTO 19).
[39] *Id.* at 4.
[40] *Id.*

Court has made no findings as to the appropriate amount of any fee awards to leadership from these holdbacks.

**F. Status Conferences**

The Court has held regular status conferences with Lead and Liaison Counsel to advance the litigation and to resolve disputes related to various discovery and other pretrial issues. To facilitate coordination of the MDL, Liaison Counsel have filed 26 Joints Reports, which detail, among other things, case inventory, discovery, and motion practice.[41] The Court has also held in-person and remote hearings to address dipositive motion practice, the bellwether trial process, and the settlement process.

**G. Settlement Committees**

The Court entered PTO 6 in December 2016, which appointed a Plaintiff Settlement Committee and a Defendant Settlement Committee. The Court directed the Settlement Committees to hold regular discussions in an attempt to resolve this matter before remand of some or all of the member cases. The Settlement Committees have conferred over the course of the MDL proceedings and have held status conferences with the Court.

The first bellwether case—*Barbara Earnest v. Sanofi U.S. Services, Inc.*—was resolved after the Fifth Circuit reversed a defense verdict and remanded the case for a new trial, and it is described in more detail below. In November 2022, the Court directed the parties to engage in "bellwether" settlement negotiations in 10 cases. These negotiations resulted in resolution of five cases. Other resolution assessment work is ongoing.

**H. Discovery**

**1. General Fact Discovery**

On August 23, 2017, this Court entered CMO 5, which governed the

[41] *See, e.g.*, Rec. Doc. 14691 (Joint Report No. 26 of Liaison Counsel).

general discovery conducted in MDL 2740.[42] The General Discovery Order culminated in monthly discovery meet-and-confer calls and hearings with Magistrate Judge Michael North.[43] The Court limited Plaintiffs to 30 depositions of Sanofi witnesses, including current and former employees and corporate representatives.[44] The deadline for general discovery against Sanofi expired on December 15, 2018.[45] The Court has denied additional general discovery requests since that time.

**a) Document Discovery**

Document discovery was governed by CMO 5 and PTO 49, the Electronically Stored Information Protocol.[46] Sanofi disclosed information on 50 potential custodians. Plaintiffs selected 36 custodians from the United States and 7 from the European Union on which to conduct discovery. After agreeing on search terms to govern the custodians selected, Sanofi produced more than 576,100 documents (or 6,320,000 pages), which included, among other things, multiple regulatory files (both in the United States and European Union), shared files, clinical trial data, MIS files, and IMS data. Many of these documents remain subject to protective orders of confidentiality, described in Part II.G.4 below.

**b) Depositions**

CMO 9 governed deposition protocol.[47] It mandated coordination of federal and state proceedings to prevent witnesses from being deposed more than once.[48] In total, 28 company witnesses from Sanofi were deposed, including Sanofi's 30(b)(6) witnesses. Multiple additional Sanofi witnesses sat

[42] Rec. Doc. 762 (Case Management Order "CMO" 5).
[43] *Id.* at 2–3.
[44] *Id.* at 4.
[45] *Id.* at 5.
[46] Rec Doc. 611 (PTO 49).
[47] Rec. Doc. 1110 (CMO 9).
[48] *Id.* at 2–3.

for deposition in case-specific work up under other orders.

Each party was directed to designate one primary examiner for each deposition. Any additional examiners were not allowed to ask a witness "the same or substantially the same question" as had been previously asked by the primary examiner.[49] During the depositions, no speaking objections were allowed, and the phrase "objection as to form" (or similar language as contemplated by Rule 30(c)(2)) was sufficient to preserve all objections.[50] Any objection made at a deposition was deemed to have been made on behalf of all other parties.[51]

**2. Case-Specific Discovery**

**a) Plaintiff Fact Sheets**

In February 2017, the Court entered PTO 18, which set forth the operable Plaintiff Fact Sheet ("PFS") and Defendant Fact Sheet ("DFS").[52] The Court then entered PTO 22, which governed the implementation of the PFS and DFS.[53] PTO 22 directed each Plaintiff to serve Defendants with a complete and verified PFS, including signed Authorizations for Release of Records of all healthcare providers, using MDL Centrality.

The PFS requested each Plaintiff provide information, including but not limited to the following topics: Plaintiff's alleged injuries; the dates upon which Plaintiff was diagnosed with cancer; the chemotherapy regimen each Plaintiff received; and Plaintiff's employment, educational, and medical history.[54] The PFS required each Plaintiff to verify the accuracy and completeness of information, and the responses in the PFS were given the same legal

[49] *Id.* at 4.
[50] *Id.* at 11–12.
[51] *Id.* at 11.
[52] Rec. Doc. 236.
[53] Rec. Doc. 270 (PTO 22).
[54] Rec. Doc. 236-1 (PTO 18, Exhibit A).

significance as answers to interrogatories.[55] The Court revised the PFS in November 2017 to require Plaintiffs to produce representative photographs of their hair during designated time periods.[56]

Concerned that certain Plaintiffs in the MDL may not have "adequately and timely produced responsive electronically stored information ("ESI")" as required by the PFS, the Court entered PTO 71 in December 2017 to govern Plaintiffs' identification, preservation, collection, and production of ESI.[57] PTO 71 outlined the relevant, potential sources of ESI ("ESI Sources") Plaintiffs should search for responsive information; mandated "reasonably diligent searches" of the ESI Sources; identified search terms each Plaintiff or her attorney would run through available search functions in the ESI Sources; and required each Plaintiff to submit a written disclosure statement to Defendants to be produced along with responsive documents.[58] In January 2018, PTO 71 was amended and superseded by PTO 71A, which was identical in substance to PTO 71 but provided Plaintiffs additional time to comply with its requirements.[59]

**b) Defendant Fact Sheets**

After receiving a substantially completed PFS, each Defendant had 75 days to send a completed DFS to MDL Centrality.[60] Because multiple Defendants are named in individual cases, raising potential product identification issues, the Court separated the cases into three categories and

[55] *Id.* at 31; *see also* Rec. Doc. 279 at 4 (PTO 22). The PFS was revised for typographical issues in PTO 38. Rec. Doc. 326.
[56] Rec. Doc. 1085 (PTO 68).
[57] Rec. Doc. 1306 (PTO 71).
[58] *Id.* at 1.
[59] Rec. Doc. 1531 (PTO 71A). The Court has permitted Sanofi to seek sanctions and costs in cases where Plaintiffs or their counsel have not complied with their case-specific discovery obligations. *See* Rec. Docs. 3917 (Order Granting Defs.' Mot. for Rule 37 Sanctions in *Gahan*); 12735 (Minute Entry); 12884 (Order); 13132 (Minute Entry).
[60] Rec. Doc. 279.

determined based on those categories which of the various Defendants were required to respond to a PFS and to what extent.[61] Absent product identification, Defendants were only required to produce limited information.[62]

Within the full DFS, Defendants were required to provide communications with the healthcare providers that treated the Plaintiff about Taxotere and hair loss. Defendants' responses on a DFS were given the same legal significance as responses to interrogatories and responses to requests for production of documents.[63]

**c) Product Identification**

On January 12, 2018, the Court entered CMO 12, later amended as CMO 12A, to enforce requirements for each Plaintiff to obtain evidence of which manufacturers' medicine she received.[64] The order created a standard form, "Statement Regarding Chemotherapy Drug Administered" for each Plaintiff to have signed by her chemotherapy infusion facility pharmacist, or other qualified custodian of record, to identify the medicine(s) used in her care by National Drug Code ("NDC").[65] Before March 2011—the period of market exclusivity of Taxotere—Sanofi manufacture was presumed, but such Plaintiffs still were required to show proof of use of Taxotere.[66] Alternatively, a Plaintiff could provide records of administration or possibly billing records identifying the medicine used in her care by NDC.[67] Under CMO 12A, Defendants were required to make their own requests in each case where the

[61] *Id.* at 4–6.
[62] *Id.* at 6.
[63] *Id.* at 8. The DFS was revised for typographical issues in PTO 38, which was entered on April 14, 2017. Rec. Doc. 326.
[64] Rec. Docs. 1506 (CMO 12); 3492 (CMO 12A).
[65] Rec. Doc. 1506 at 2.
[66] *Id.* at 4–6. Certain conditions could create an exception, such as enrollment in a clinical trial. *Id.*
[67] *Id.* Defendants had earlier been ordered to provide charts of their NDCs and market dates, as well as their distributors. Rec. Doc. 298 at 2 (PTO 27).

Plaintiff's efforts were unavailing.[68] The Court eventually instituted a Show Cause process for Plaintiffs who had failed to undertake product identification efforts or Plaintiffs for whom such information was unavailable, had been lost, or was not maintained, after a period of potential third-party discovery of facility custodians and/or distributors.[69]

**d) Photographs and Show Cause Process**

Over time, the Court has gained particular expertise in evaluating photographs submitted by Plaintiffs as proof of their alleged injury. Under PTO 68, the Court required Plaintiffs to produce dated photographs that depict their hair within five years of starting chemotherapy, during chemotherapy (if available), within five years of completing chemotherapy, and recent photographs.[70] Central to the difficulty of this evaluation has been the fact that some Plaintiffs suffered a recurrence of cancer and potentially began another chemotherapy regimen. This issue dictated an additional requirement for Plaintiffs who experienced a recurrence of cancer to produce photographs

[68] Rec. Doc. 3492 at 4.
[69] Rec. Doc. 13587 (Order to Show Cause Regarding CMO-12A Product Identification). The Court deferred dismissal of "no product identification" cases in a small handful of jurisdictions (California, Illinois, and Massachusetts) that Plaintiffs argued potentially recognized "innovator" liability. Rec. Doc. 14174 at 4 (Minute Entry); *see also* Rec. Docs. 14312 (Pl.'s Show Cause Response—Innovator Liab. Under Cal. Law); 14316 (Pl.'s Show Cause Response—Innovator Liab. Under Ill. Law); 14313 (Pl.'s Show Cause Response—Innovator Liab. Under Mass. Law). In response, Sanofi asserted that 505(b)(2) manufacturers are not Abbreviated New Drug Application ("ANDA") holders for labeling purposes, that 505(b)(2) or generic manufacturers may have copied each other's labels, and that innovator liability was not pleaded in the Master Complaint or individual short form complaints, nor was it included in general or case-specific work up. Rec. Docs. 14398 (Defs.' Resp. in Opp. to Pl.'s Show Cause Response—Innovator Liab. Under Cal. Law); 14400 (Defs.' Resp. in Opp. to Pl.'s Show Cause Response—Innovator Liab. Under Ill. Law); 14399 (Defs.' Resp. in Opp. to Pl.'s Show Cause Response—Innovator Liab. Under Mass. Law).
[70] Rec. Doc. 1085 (PTO 68).

between such treatments, in order to determine whether their hair regrew before or after taking Taxotere.[71]

Apart from photograph issues, the Court issued PTO 22A on July 24, 2018, which governed Defendants' requests to dismiss the cases of Plaintiffs who allegedly failed to submit a complete and verified PFS.[72] Specifically, PTO 22A addressed Plaintiffs who failed to complete a PFS, who failed to sign authorizations, who failed to pursue or obtain product identification (as described above), who had passed away without substitution, or who had other problems of basic proof.[73] All told, the Show Cause process has resulted in dismissal of more than 3,000 cases.

**e) Pathology Protocol**

CMO 15 discussed pathology protocol and required Plaintiffs who had a scalp biopsy to send a preservation letter to the applicable facilities.[74] It also provided for the sharing of specimens amongst the parties, among other issues to diagnose Plaintiffs' alleged injuries.[75]

**3. Expert Discovery**

In June 2018, the Court entered CMO 14, which provided a schedule to identify and select Plaintiffs for a succession of bellwether trials.[76] The Court required the parties to disclose their general and specific expert reports.[77]

[71] *See* Hr'g. Tr. 36–37 (July 9, 2021). Photographs have also been used to evaluate a Plaintiff's hair regrowth where Plaintiff began taking anti-hormonal therapy following chemotherapy.
[72] Rec. Doc. 3493 (PTO 22A).
[73] *Id.* at 1.
[74] Rec. Doc. 5008 at 1–2 (CMO 15).
[75] *Id.* at 2–3.
[76] Rec. Doc. 3064 (CMO 14).
[77] *Id.* at 2–3.

Since the first bellwether trial, several of the parties' experts have issued additional reports and have been deposed for subsequent bellwether cases.[78]

In April 2022, the Court granted the PSC's Motion to Preserve Expert Testimony[79] and later entered CMO 36. CMO 36 set out the protocols to preserve general expert testimony by video for potential use in remanded cases.[80] Under CMO 36, expert preservation deposition testimony is "subject to the Court's prior rulings as they relate to these witnesses," including the Court's Rule 702 rulings.[81] In addition, the Court did not pre-adjudicate issues related to admissibility or availability—for example, whether the parties may introduce preservation deposition testimony at trial.[82] *See* Fed. R. Evid. 804. The parties have completed the preservation depositions of two of Plaintiffs' experts. Preservation depositions, including depositions of Sanofi's experts, may continue in this Court after the entry of this Order. Further, the parties have not conducted case-specific expert discovery in the cases to be remanded, and the remand courts should set a schedule for the completion of case-specific expert discovery.

**4. Protective Order and Confidentiality**

A stipulated protective order governing the designation, handling, use, and disclosure of confidential discovery material was entered on July 5, 2017.[83]

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[78] The Court provides a summary of these experts and the Court's rulings on the admissibility of their opinions in Part II.J.8.
[79] Rec. Doc. 13981 (Order Granting PSC's Mot. to Preserve Expert Test.).
[80] Rec. Doc. 14925 (CMO 36).
[81] *Id.* at 1–2, 6.
[82] *Id.* at 2. If a receiving court determines that a party may introduce preservation deposition testimony at trial consistent with the Federal Rules of Evidence, the Court cautions the receiving court to analyze any proposed testimony at trial in light of this Court's Rule 702 and motions in limine rulings.
[83] Rec. Doc. 612 (PTO 50).

The Court also entered a stipulated ESI Protocol, which governed many aspects of electronically stored information.[84]

Prior to the Fifth Circuit's decision in *Le v. Exeter*, this Court routinely sealed pleadings at the parties' unopposed requests pursuant to the stipulated protective order.[85] Based on the Fifth Circuit's ruling, the Court applies the requisite particularity set forth in *Le* for sealing documents and will hear any motions to unseal documents consistent with the guidance set forth in the *Le* decision.[86] The transferor court will decide the issue on sealing of documents according to the governing law in the Circuit.

### I. Bellwether Cases and Trials

On a parallel track to general discovery, the Court directed the parties to begin the case-specific workup of trial pools for bellwether trials. Initially, the Court contemplated four bellwether trials in 2019 as set forth in Case Management Order Nos. 3, 4 & 6.[87] The presiding transferee Judge Kurt D. Engelhardt was then appointed to the United States Fifth Circuit Court of Appeals and the MDL was reassigned to the Honorable Jane Triche Milazzo, who has presided as transferee Judge since May 15, 2018.[88] This Court crafted a new scheduling order that contemplated five bellwether trials comprised of both the initially selected Trial Plaintiffs and additional nominations whose claims would be adjudicated in a succession of trials.[89] Both *Lexecon* and the ability of the Court to try a case in a jurisdiction other than the Eastern District

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[84] Rec. Doc. 611.
[85] Rec. Doc. 612 (PTO 50).
[86] Binh Hoa Le v. Exeter Fin. Corp., 990 F.3d 410, 417-421 (5th Cir. 2021).
[87] Rec. Docs. 669, 670, 780.
[88] Rec. Doc. 464.
[89] *See* CMO 14 (Doc. 3064), et seq. CMO 14A (Doc. 5035), CMO 14B (Doc. 6788), CMO 14C (Doc. 6789), CMO 14D (Doc. 7416), CMO 14E (Doc. 9367), CMO 14F (Doc. 9631), CMO 14G (Doc. 10985), CMO 14H (Doc. 11392), CMO 14I (Doc. 12283), CMO 14J (Doc. 12760), CMO 14J (Doc. 13195), CMO 14K (Doc. 13199), CMO 14L (Doc. 13298), CMO 14M (Doc. 13468), CMO 14N (Doc. 14240).

of Louisiana were forefront in the nomination or selection of bellwether Plaintiffs.

Following completion of limited "Phase I" discovery, four trial Plaintiffs were selected by the Court for the first trial, and deadlines for pre-trial matters such as general and specific expert reports, the exchange of "materials relied upon", depositions, briefing schedule for dispositive or Daubert Motions, and the schedule for trial preparation documents, and setting the trial date were set. Based on the submission to the Court by Sanofi and Plaintiffs, the Court selected additional Plaintiffs for the next trial pools, as well as setting forth the procedure for the nomination of trial Plaintiffs following completion of Phase I bellwether workup. The Court emphasized that the nominated trial Plaintiffs must be representative of the characteristics of the claims in the MDL. The Court intended to hold five trials – three involving Sanofi (including one where the Court would sit by designation in Mississippi), and two involving the 505(b)(2) defendants. Ultimately, two Louisiana Plaintiffs' cases involving Sanofi proceeded as bellwether trials.

The first bellwether trial (*Earnest v. Sanofi*) was held in September 2019. The jury found in favor of the defense.[90] The Plaintiffs appealed, and the Fifth Circuit Court of Appeals reversed and returned the case to the district court.[91] On remand, with motion practice pending, the *Earnest* matter resolved in settlement in 2022.

The second bellwether trial (*Kahn v. Sanofi*) proceeded in November 2021 and the jury returned a defense verdict.[92] The plaintiff has sought Rule 60(b) relief given her position that pretrial rulings similar to those in *Earnest*

[90] Doc. 8284.
[91] *In re* Taxotere (Docetaxel) Prod. Liab. Litig., 26 F.4th 256 (5th Cir. 2022).
[92] Doc. 13436.

prejudiced her ability to fairly present evidence in her trial. That motion remains pending.

**J. Wave Workup**

In CMO 33, the Court began the process of remanding and/or transferring the cases still pending in the MDL to their appropriate trial courts.[93] CMO 33 outlined the process for selection and discovery of the first 200 cases, which became the "Wave 1" cases.[94] Wave 1 was limited to cases where the Plaintiffs had identified in their PFS only brand name Taxotere and/or Winthrop.[95] Wave 1 selection criteria also included the following: no cases involving deceased Plaintiffs; no cases where treatment took place either before December 15, 2006, or after December 11, 2015; and no cases where the Plaintiff was prescribed or administered Taxotere in Michigan, Louisiana, Mississippi, or Texas.[96] CMO 34 listed the selected cases.[97]

Discovery in Wave 1 was limited to certain supplemental discovery and up to four depositions, including (1) Plaintiff; (2) Plaintiff's prescribing physician; (3) Plaintiff's treating physician (if any); and (4) one sales representative who called on Plaintiff's healthcare provider.[98]

On June 13, 2022, after an initial hearing and challenges to case eligibility, the Court re-categorized the cases in Wave 1 into (1) cases proceeding with Wave 1 remand discovery and (2) cases not proceeding with Wave 1 remand discovery.[99] In CMO 34B, issued on August 26, 2022, the Court

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[93] Rec. Doc. 13946 (CMO 33).
[94] *Id.*
[95] *Id.* at 2.
[96] *Id.* at 2–3. Cases where the Plaintiff was prescribed or administered Taxotere in Michigan has previously been dismissed on state-law grounds. *See* Rec. Doc. 13327 (Minute Order) (dismissing with prejudice 355 cases from Michigan pursuant to the Michigan Products Liability Act).
[97] Rec. Doc. 14045 (CMO 34).
[98] Rec. Doc. 13946 at 5.
[99] Rec. Doc. 14292 (CMO 34A).

designated cases as either Plaintiff or Sanofi-priority cases for purposes of physician deposition scheduling and examination order.[100] And on February 23, 2023, this Court entered CMO 34C, which reflected only 98 cases proceeding with Wave 1 discovery and extended the deadline for completing Wave 1 discovery to February 28, 2023.[101]

### K. Key Legal and Evidentiary Rulings

#### 1. Fencepost Rulings

In early 2020, Sanofi filed two "fencepost motions"[102]—motions for summary judgment seeking dismissal of cases where Plaintiffs were treated with Taxotere before December 15, 2006 ("pre-2007 motion")[103] and after December 2015 ("post-2015 motion").[104] With respect to the pre-2007 motion, Sanofi argued for dismissal because Plaintiffs' regulatory expert (Dr. David Kessler, former FDA Commissioner) opined that Sanofi should have warned of permanent alopecia as of December 2006.[105] The pre-2007 motion related to approximately 1,400 cases.[106] The Court, recognizing some differences between state laws, elected to analyze the issue with respect to Louisiana Plaintiffs by way of example.[107] The Court held that the Louisiana Plaintiffs failed to create a genuine issue of material fact supporting their pre-2007 claims because they could not prove Sanofi had "knowledge" that Taxotere potentially caused

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[100] *Id.* at 2.
[101] Rec. Doc. 15547 (CMO 34C).
[102] The Court uses the term "fencepost motions" to describe motions that set parameters for groups of cases contained in the MDL. In this instance, there was a pre-2007 fencepost motion and a post-2015 fencepost motion.
[103] Rec. Doc. 8977 (Defs.' Mot. for Summ. J. on the Claims of Pls. Whose Taxotere Treatment Started Before December 15, 2006) ("Pre-2007 Mot.").
[104] Rec. Doc. 9268 (Defs.' Mot. for Summ. J. on the Claims of Pls. Whose Taxotere Treatment Started After December 11, 2015) ("Post-2015 Mot.").
[105] Rec. Doc. 8977-2 at 5–13 (Mem. in Supp. of Defs.' Pre-2007 Mot. for Summ. J.).
[106] Rec. Doc. 8977-3 (Exhibit A to Defs.' Pre-2007 Mot. for Summ. J.).
[107] Rec. Doc. 10487 at 4–5 (Order Granting in Part and Deferring in Part Defs.' Pre-2007 Mot. for Summ. J.).

permanent alopecia before December 2006.[108] The Court dismissed the Louisiana cases and instructed the parties to submit supplemental briefing on which states have similar requirements as Louisiana, which has been completed.[109]

With respect to the post-2015 motion, Sanofi argued that its labeling as of December 2015, which warned that "cases of permanent alopecia have been reported," was adequate as a matter of law because the label clearly and accurately described permanent alopecia as a known risk of Taxotere.[110] This motion related to approximately 200 cases.[111] The Court held that the Taxotere label after December 2015 adequately warned of permanent alopecia, and the Court granted summary judgment on Plaintiffs' failure-to-warn claims.[112]

**2. Preemption**

The Court has ruled on two preemption motions filed by Sanofi in the MDL. These motions turned on the issue of impossibility preemption—that is, whether it was impossible for Sanofi to have updated its label under the Federal Food, Drug, and Cosmetic Act before certain Plaintiffs' dates of treatment. Before Ms. Earnest's bellwether case, the Court denied in part and deferred in part Sanofi's summary judgment motion based on preemption.[113] Sanofi asserted that at the time Ms. Earnest received Taxotere in 2011, federal law prevented Sanofi from unilaterally adding different warning language to the Taxotere labeling.[114] The Court, however, found that Sanofi had not shown any attempt to update its labeling through the federal Change Being Effected

[108] *Id.* at 7–9.
[109] *Id.* at 9–10.
[110] Rec. Doc. 9268-2 at 7–14 (Mem. in Supp. of Defs.' Post-2015 Mot. for Summ. J.).
[111] Rec. Doc. 9268-3 (Exhibit A to Defs.' Post-2015 Mot. for Summ. J.).
[112] Rec. Doc. 10464 at 5–6 (Order Granting Defs.' Post-2015 Mot. for Summ. J.).
[113] Rec. Doc. 7973 (Order Denying in Part and Deferring in Part Defs.' Mot. for Summ. J. Based on Preemption in *Earnest*). The Court deferred ruling on preemption as it related to other Plaintiffs in the MDL.
[114] *Id.* at 2.

regulation, nor did Sanofi present "clear evidence" that the FDA would not have approved a change to the Taxotere label.[115] The Court considered evidence Sanofi had submitted to FDA in 2004 and 2009, but it did not find that "Sanofi was trying to alert the FDA of an uptick in reports of permanent alopecia."[116]

Before Ms. Kahn's bellwether trial, the Court granted in part and denied in part Sanofi's summary judgment based on preemption.[117] Sanofi asserted that it could not update its label before Ms. Kahn's treatment in 2008.[118] Specifically, Sanofi identified the results of two clinical trials and two scientific publications that Sanofi had provided to FDA before 2004 that, according to Sanofi, "disclosed data and reports of alopecia, including reports of patients with ongoing, persistent, or nonreversible alopecia following treatment with combination chemotherapy regimens that included Taxotere."[119] The Court, however, found that an abstract published in 2006 constituted "newly acquired information" that would have supported a label change under the federal Changes Being Effects regulation.[120] The Court then analyzed the "clear evidence" prong of the impossibility preemption framework. The Court held federal law preempted Ms. Kahn's claim that Sanofi should have included permanent alopecia in the Warnings and Precautions section of the Taxotere label because there was clear evidence FDA would have rejected such a claim based on communications between Sanofi and FDA in 2015.[121] Based on these rulings, the Court permitted Ms. Kahn to proceed with a claim that Sanofi

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[115] *Id.* at 8.
[116] *Id.* at 9.
[117] Rec. Doc. 11682 (Order Granting in Part and Denying in Part Defs.' Mot. for Summ. J. Based on Preemption in *Kahn*).
[118] *Id.* at 14.
[119] *Id.*
[120] *Id.* at 19.
[121] *Id.* at 20–21.

should have updated the Adverse Reactions section of the Taxotere label to include the language later approved in 2015, back at the time of Ms. Kahn's treatment.[122]

### 3. Proof of Diagnosis

In July 2020, Sanofi filed a Motion for Entry of an Order Requiring Proof of Diagnosis.[123] The proposed order would have required each Plaintiff to submit either evidence of a medical diagnosis of PCIA caused by Taxotere or state that Plaintiff did not intend to pursue such a diagnosis.[124] Approximately 80 percent of MDL Plaintiffs do not have medical evidence of their alleged hair loss injury or causation.[125] Following a lead and liaison conference in August 2020, the Court deferred ruling on Sanofi's motion, subject to being re-urged after the third bellwether trial.[126] After the Court dismissed the third bellwether Plaintiffs, Sanofi re-urged its motion in February 2022.[127] The Court, however, entered CMO 33 in March 2022, which began Wave 1 work-up.[128]

### 4. General Causation

This Court has also addressed general causation as it relates to both bellwether trials.[129] To prevail on their claims, Plaintiffs must establish general causation through reliable expert testimony.[130] General causation

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[122] *Id.* at 21–22.
[123] Rec. Doc. 10808 (Defs.' Mot. for Entry of an Order Requiring Proof of Diagnosis).
[124] *Id.* at 1.
[125] Rec. Doc. 10808-1 at 1 (Mem. of Law. in Supp. of Defs.' Mot. for Entry of an Order Requiring Proof of Diagnosis). PCIA requires a differential diagnosis. *Id.* at 5–9.
[126] Rec. Doc. 10908 (Order Deferring Defs.' Mot. for Entry of an Order Requiring Proof of Diagnosis).
[127] Rec. Doc. 13912 at 5 (Defs.' Remand Proposal).
[128] Rec. Doc. 13946.
[129] Rec. Docs. 8094 (Order and Reasons Denying Mot. to Exclude Expert Test. on General Causation in *Earnest*); 11685 (Order and Reasons Denying Pl.'s Motion for Partial Summ, J. on Causation in *Kahn*).
[130] Rec. Doc. 8094 at 5.

requires a Plaintiff to meet a two-pronged test under Louisiana law: (1) there must be evidence showing a "statistically significant association" between the agent and the disease, and (2) there must be a causal relationship that underlies the association.[131]

In Ms. Earnest's case, Sanofi argued that Plaintiff had failed to establish general causation because Plaintiff's experts, Dr. Madigan and Dr. Feigal, did not analyze or set out a methodology in their expert reports that would be sufficient to establish general causation.[132] This Court held that Plaintiff had presented evidence to establish both prongs by relying on Dr. Madigan to identify a statistically significant association between Taxotere and the alleged injury, and Dr. Feigal to establish a causal association using the Bradford Hill criteria.[133]

In Ms. Kahn's case, Plaintiff sought partial summary judgment, requesting this Court find as a matter of law that "Taxotere can cause permanent alopecia."[134] Plaintiff argued that because Sanofi communicated to FDA in 2015 that enough evidence existed to support a "causal association" between Taxotere and permanent alopecia and because of Dr. Madigan and Dr. Feigal's testimony, no reasonable jury could find that Taxotere does not cause permanent hair loss.[135] The Court disagreed, noting that that the 2015 correspondence between FDA and Sanofi was not an admission of causation and that Sanofi had provided its own experts who presented "reliable evidence to rebut Plaintiff's contentions."[136]

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[131] *Id.* at 5.
[132] Rec. Doc. 6163 (Defs.' Mot. to Exclude Expert Test. on General Causation in *Earnest*).
[133] Rec. Doc. 8094 at 5–6. The Bradford Hill criteria are: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. *Id.* at 5.
[134] Rec. Doc. 11685 at 2.
[135] *Id.* at 3.
[136] *Id.*

Accordingly, in both bellwether trials, this Court held that general causation could not be determined as a matter of law and therefore should be decided by the jury after hearing the testimony of each party's experts.

**5. Statute of Limitations**

The Court has addressed numerous statute of limitations motions over the course of the MDL, and the Fifth Circuit has also considered several appeals on the statute of limitations.[137]

In July 2019, the Court ruled on motions for summary judgment based on the statute of limitations in three bellwether cases under Louisiana law.[138] In Louisiana, the statute of limitations for products liability claims is one year.[139] The Court first looked to Plaintiffs' Master Complaint, which defined the injury of permanent alopecia as manifesting six months after the completion of chemotherapy.[140] In each case, Plaintiffs filed their lawsuits in 2016—several years after completing chemotherapy—after learning of the link between Taxotere and permanent alopecia through advertisements and social media.[141] Because Plaintiffs' claims were time-barred on their face, the Court next considered whether the Louisiana doctrine of *contra non valentem* (or the "discovery rule") applied, which states that the statute of limitations begins to run when a plaintiff has "actual or constructive knowledge of facts indicating to a reasonable person that he or she is a victim of a tort."[142]

In Plaintiff Deborah Johnson's case, the Court reasoned that Ms. Johnson completed her chemotherapy in 2010 and testified that she did not think anything other than her chemotherapy caused her hair loss and that she

[137] Part II.J.7 provides an overview of the appellate decisions on statute of limitations.
[138] Rec. Doc. 7571. Three of the motions requested summary judgment based on the learned intermediary doctrine. *Id.* at 1.
[139] *Id.* at 4 (citing La. Civ. Code Art. 3492).
[140] *Id.* at 2–3.
[141] *Id.* at 3.
[142] *Id.* at 5.

became very concerned that her hair might not grow back at all as early as 2010.[143] Finding no evidence that Ms. Johnson investigated her injury before filing her lawsuit in 2016, the Court granted summary judgment in Sanofi's favor.[144] Likewise, in Plaintiff Tanya Francis's case, the Court found that Ms. Francis's allegations made "clear that she recognized the severity of her symptoms and that she attributed her hair loss to her chemotherapy."[145] Because Ms. Francis had a duty to investigate and failed to do so, the Court held that the *contra non valentem* doctrine did not apply and her claims were time-barred.[146]

The Court denied summary judgment on the statute of limitations in Plaintiff Barbara Earnest's case.[147] The Court distinguished Ms. Earnest's case, finding that she inquired with her doctor about her injury and was led to believe that her hair was just taking more time to regrow, until 2016.[148] As a result, an issue of fact remained for the jury to decide, and Ms. Earnest's case proceeded as the first bellwether trial.

In January 2020, the Court granted summary judgment on the statute of limitations in Plaintiff Cynthia Thibodeaux's case.[149] Ms. Thibodeaux completed chemotherapy in June 2009, and the Master Complaint defined her injury of PCIA as manifesting six months after chemotherapy.[150] Because the one-year limitations period ended in January 2011, the Court held that Ms. Thibodeaux's case filed in October 2016 was time-barred on its face.[151] The

[143] *Id.* at 6.
[144] *Id.* at 6, 26.
[145] *Id.* at 10.
[146] *Id.*
[147] *Id.* at 8.
[148] *Id.*
[149] Rec. Doc. 9110 (Order Granting Defs.' Mot. for Summ. J. in *Thibodeaux*).
[150] *Id.* at 4–5.
[151] *Id.* at 5.

Court also held that the *contra non valentem* doctrine was inapplicable.[152] Ms. Thibodeaux "had actual or constructive knowledge of a causal relationship between her injury and Taxotere, yet she did nothing to investigate."[153]

In April 2020, the Court denied summary judgment on the statute of limitations in Plaintiff Elizabeth Kahn's case, which proceeded as the second bellwether trial.[154] Although the Court found that Ms. Kahn's case was time-barred on its face, the Court held that there was an issue of fact under the *contra non valentem* doctrine.[155] Specifically, the Court found that Ms. Kahn may have had reason to believe that something other than Sanofi's conduct caused her injury because Ms. Kahn's gynecologist told Ms. Kahn that her hair loss may be due to age.[156]

In July 2020, the Court granted summary judgment on the statute of limitations under Louisiana law in Plaintiff Antoinette Durden's case.[157] The Court held that Ms. Durden's case was time-barred on its face.[158] The Court further found that Ms. Durden "suspected something was wrong and yet failed to investigate its cause."[159] Although Ms. Durden sought treatment from her doctors for her hair loss, the Court found that this alone was insufficient.[160] Without evidence showing that any of Ms. Durden's doctors told her, after her treatment, that regrowth can take time or that something else was causing her injury, the *contra non valentem* doctrine did not apply.[161]

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[152] *Id.*
[153] *Id.*
[154] Rec. Doc. 9885 (Order Denying Defs.' Mot. for Summ. J. Based on the Statute of Limitations in *Kahn*).
[155] *Id.* at 6.
[156] *Id.* at 7–8.
[157] Rec. Doc. 10833 (Order Granting Defs.' Mot. for Summ. J. in *Durden*).
[158] *Id.* at 3.
[159] *Id.* at 5.
[160] *Id.*
[161] *Id.* at 5–6.

The Court has also issued statute of limitations rulings under Mississippi law. In January 2021, the Court granted Sanofi's motion for judgment on the pleadings and dismissed Plaintiff Juanita Greer's case, finding her claims were time-barred by the three-year statute of limitations under Mississippi law.[162] The Court rejected Ms. Greer's argument that the discovery rule and the fraudulent concealment exception applied to toll the statute of limitations in her case.[163] Specifically, the Court held that the discovery rule only applied to cases involving latent injuries under Mississippi law. Because the pleadings established Ms. Greer's injury was open and obvious, the discovery rule could not toll her claims.[164] The Court further held that the fraudulent concealment exception did not apply because Ms. Greer did not plead that Sanofi prevented her from discovering her claim, as required by Mississippi law, but rather that Sanofi prevented her from discovering Taxotere's risk of permanent hair loss.[165]

The Court later granted Sanofi's motions for summary judgment in Plaintiffs Melissa Roach and Cindy Smith's cases for the reasons articulated in Ms. Greer's case.[166] Following a show cause process, the Court dismissed the claims of 223 Mississippi Plaintiffs under the statute of limitations.[167] Sanofi urged 12(c) motions in five additional states—Alabama, Idaho, North Carolina, North Dakota, and Virginia—citing the absence of any discovery rule in those

[162] Rec. Doc. 12057 (Order Granting Defs.' Mot. for J. on the Pleadings Based on the Statute of Limitations in *Greer*).
[163] *Id.*
[164] *Id.* at 6.
[165] *Id.* at 8.
[166] Rec. Docs. 12718 (Order Granting Defs.' Mot. for Summ. J. Based on the Statute of Limitations in *Roach*); 13064 (Order Granting Defs.' Mot. for Summ. J. Based on the Statute of Limitations in *Smith*).
[167] Rec. Doc. 15322 (Order Denying Mot. for Recons. by Pls. Whose Cases Were Dismissed by this Court's Orders of July 13, 2022 and July 18, 2022).

states, which the Court denied without prejudice.[168]

**6. Warnings Causation**

Warnings causation has also played in a prominent role in bellwether motion practice. The Court summarizes several key decisions below. In addition, the Fifth Circuit Guidance section provides appellate decisions on warnings causation.

In Ms. Earnest's case, the Court denied Sanofi's motion for summary judgment based on warnings causation in July 2019.[169] Under Louisiana law, inadequate warning claims are governed by a two-prong test.[170] The plaintiff must first show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product not otherwise known to the physician.[171] Second, the plaintiff must show that the failure to warn was both the cause in fact and proximate cause of the plaintiff's injury.[172] The Court noted that Ms. Earnest's oncologist testified that he could choose either Taxotere or Taxol to treat Ms. Earnest.[173] Based on Ms. Earnest's testimony that she would have relied on her oncologist to prescribe an equally effective drug as Taxotere if she had the option, the Court found that the oncologist and Ms. Earnest's testimony created an issue of fact on whether Ms. Earnest would have still chosen Taxotere despite knowing of its risks of permanent alopecia.[174]

The Court granted Sanofi's motion for summary judgment on warnings

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[168] Rec. Doc. 14207 (Order Denying Without Prejudice Defs.' Mot. for J. on the Pleadings as to the Claims of Beverly Dickerson, Catherine Hurrell, Annie Johnson, JoAnn Coates, and Margaret Bailey).
[169] Rec. Doc. 7571 at 20 (*Earnest*).
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.* at 20–21.
[174] *Id.* at 21.

causation in Plaintiff Kelly Gahan's case in March 2020.[175] Deciding the issue under Colorado law, the Court dismissed Ms. Gahan's failure-to-warn claims, finding that Ms. Gahan was aware of the risk of permanent hair loss and nonetheless proceeded with a Taxotere regimen.[176] As a result, the Court held that Ms. Gahan had failed to create an issue of fact on whether her oncologist's prescribing decision would have changed had Sanofi provided a different warning.[177]

In April 2020, the Court denied Sanofi's motion for summary judgment on warnings causation in Ms. Kahn's case.[178] The Court found that Ms. Kahn's oncologist testified that he would discuss other chemotherapy options with a patient if she did not wish to take Taxotere after learning of a potential risk of permanent hair loss and that Taxol was an adequate alternative in terms of efficacy.[179] In addition, Ms. Kahn testified that, had she been aware of the risk, she would have asked what her other options were.[180] Taken together, the Court held that there were fact issues for the jury to decide on warnings causation.[181] Following a decision by the Fifth Circuit on warnings causation in Plaintiff June Phillips's case, Sanofi moved for reconsideration of this Court's order in Ms. Kahn's case, which the Court denied.[182]

The Fifth Circuit's decision in Ms. Phillips's case affirmed this Court's grant of summary judgment on warnings causation in April 2020.[183] In Ms. Phillips's case, her oncologist testified that there were no adequate non-

[175] Rec. Doc. 9440 (Order Granting Defs.' Mot. for Summ. J. Based on the Learned Intermediary Doctrine in *Gahan*).
[176] *Id.* at 8.
[177] *Id.*
[178] Rec. Doc. 9888 (*Kahn*).
[179] *Id.* at 4–5.
[180] *Id.* at 5.
[181] *Id.*
[182] Rec. Doc. 13062 (Order Denying Defs.' Mot. for Recons. on Warnings Causation).
[183] Rec. Doc. 9887 (*Phillips*).

Taxotere regimens to treat Ms. Phillips's aggressive cancer.[184] As a result, this Court held that even with an adequate warning, the evidence demonstrated that Ms. Phillips and her oncologist would have decided on a Taxotere regimen to treat her cancer.[185]

In July 2020, in Plaintiff Antoinette Durden's case, the Court denied summary judgment on warnings causation grounds.[186] The Court held that the evidence suggested that Ms. Durden's oncologist would have warned Ms. Durden of Taxotere's risks, and she would have discussed and respected any concerns that Ms. Durden had about the risks.[187] As a result, the Court found that warnings causation was a question for the jury.[188]

The Court granted Sanofi's motion for summary judgment on warnings causation in Plaintiff Emma Willie's case in April 2021.[189] Applying Mississippi law, the Court found that Ms. Willie's oncologist would still have recommended today the same Taxotere-containing regimen that he recommended to her in 2014.[190] And based on Ms. Willie's testimony that she was focused on survival and trusted her oncologist, the Court concluded that "a reasonable jury could only find that Willie would not have gone against [her oncologist's] recommendation to take a Taxotere-containing regimen, even if it meant risking permanent hair loss."[191]

**7. Michigan Cases**

At defendants' request, the Court entertained a non-bellwether motion for summary judgment in a single case of defendants' choosing where

[184] *Id.* at 4.
[185] *Id.* at 6.
[186] Rec. Doc. 10832 (Order Granting in Part and Denying in Part Defs.' Mot. for Summ. J. Based on the Learned Intermediary Doctrine in *Durden*).
[187] *Id.* at 6–7.
[188] *Id.* at 7.
[189] Rec. Doc. 12491 (*Willie*).
[190] *Id.* at 4.
[191] *Id.* at 8.

Michigan's product liability law applied with the caveat that the ruling would be applied generally for Michigan cases. The Court granted summary judgment, finding the Michigan Products Liability Act precluded the Plaintiff's claim.[192] The Court held a show cause proceeding in which Plaintiffs were required to appear and show cause why the *Mixon* ruling did not preclude their action where Michigan substantive law applied.[193] Some Plaintiffs objected on choice-of-law grounds. Those issues have been deferred for the transferor courts to determine.[194]

### 8. Fifth Circuit Guidance

The Fifth Circuit has also issued decisions addressing appeals from the MDL, primarily on statute of limitations and warnings causation issues.

On April 19, 2021, the Fifth Circuit affirmed this Court's dismissal of Ms. Phillips's case based on warnings causation.[195] The Fifth Circuit held that there was insufficient evidence to create a dispute as to whether a warning for permanent alopecia would have changed Ms. Phillip's doctor's prescribing decision.[196] Ms. Phillips's prescribing physician testified that he would have recommended the same treatment for Ms. Phillips even if the label had included a warning for permanent alopecia.[197] The Fifth Circuit further clarified the application of warnings causation under Louisiana law, declining to adopt Ms. Phillips's argument that it should consider whether the Plaintiff's role in treatment would have changed the prescribing physician's counseling—as opposed to his or her recommendation—upon learning about permanent alopecia.[198] Ms. Phillips filed a petition for *en banc* review of the Fifth Circuit's

[192] *See* Order and Reasons in *Mixon* (Doc 12405).
[193] Doc. 13327.
[194] Doc. 14454.
[195] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips), 994 F.3d 704, 706 (5th Cir. 2021).
[196] *Id.* at 709.
[197] *Id.*
[198] *Id.* at 708–09.

decision on May 3, 2021, which was denied.[199]

On April 21, 2021, the Fifth Circuit affirmed this Court's dismissals of the claims of Ms. Francis, Ms. Thibodeaux, and Ms. Johnson based on the statute of limitations.[200] The Fifth Circuit held that the three Plaintiffs' claims were facially prescribed and that *contra non valentem* did not toll Plaintiffs' claims because they did not act reasonably in failing to investigate their claims.[201] The Fifth Circuit stated, "[a] reasonable inquiry into the cause of one's persistent hair loss would likely include consultation with doctors, but a plaintiff with persistent hair loss might instead search for the cause herself."[202] The Fifth Circuit also highlighted a number of internet sources, medical literature, and news articles discussing persistent alopecia associated with Taxotere that were available to Plaintiffs before their claims expired.[203] On May 5, 2021, Plaintiffs sought *en banc* review of the decision, which was denied.[204]

On June 9, 2021, the Fifth Circuit affirmed this Court's dismissal of Ms. Durden's claims on statute of limitations grounds.[205] Following its decision in *Thibodeaux*, the Fifth Circuit found that Ms. Durden had sustained her injury six months after chemotherapy.[206] The Fifth Circuit further held that that *contra non valentem* did not apply in Ms. Durden's case because she "never

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[199] Appellant's Pet. Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips)*, No. 20-30405 (5th Cir. May 3, 2021); Denial of Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips)*, No. 20-30405 (5th Cir. May 24, 2021).
[200] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Thibodeaux), 995 F.3d 384, 387 (5th Cir. 2021).
[201] *Id.* at 392–94.
[202] *Id.* at 393.
[203] *Id.* at 393–94.
[204] Appellants' Pet. for Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Thibodeaux)*, No. 20-30104 (5th Cir. May 5, 2021); Denial of Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Thibodeaux)*, No. 20-30104 (5th Cir. June 1, 2021).
[205] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Durden), 860 F. App'x 886, 887 (5th Cir. 2021).
[206] *Id.* at 890–91.

explored' Taxotere as a possible explanation for her persistent hair loss."[207]

On July 1, 2021, the Fifth Circuit affirmed this Court's dismissal of Ms. Gahan's clams.[208] The Fifth Circuit reasoned that Ms. Gahan could not establish that Sanofi's alleged failure to warn was a proximate cause of her injury.[209] Because both Ms. Gahan and her doctor were specifically aware of the risk of permanent hair loss before Ms. Gahan received Taxotere, the Fifth Circuit held that "[a] reasonable person, with all of the information that Gahan possessed, would not have changed her mind by reading a warning that told her what she already knew."[210]

### 9. Rule 702 Rulings

#### a) Plaintiffs' Experts

The Court assessed the opinions of Plaintiffs' experts under Rule 702 before both bellwether trials. In *Earnest*, Plaintiff called at trial Dr. David Kessler, Dr. David Madigan, Dr. Laura Plunkett, Dr. Antonella Tosti, Dr. Ellen Feigal, and Dr. Linda Bosserman. In *Kahn*, Plaintiff called at trial Dr. Linda Bosserman, Dr. Antonella Tosti. Dr. Laura Plunkett, Dr. Ellen Feigal, and Dr. David Madigan.

**David Madigan, PhD.** Dr. David Madigan is a biostatistician who the Court permitted to opine on whether there was a statistically significant association between Taxotere and PCIA (the first prong of general causation).[211] The Court found Dr. Madigan's methods—including his search

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[207] *Id.* at 892 (cleaned up).
[208] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Gahan), 859 F. App'x 692, 695 (5th Cir. 2021).
[209] *Id.* at 694.
[210] *Id.*
[211] Rec. Docs. 8094 at 4–7 (Order Denying Defs.' Mot. to Exclude Expert Test. on General Causation, Denying Defs.' Mot. to Exclude Expert Test. of Madigan, and Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Feigal in *Earnest*); 12098 at 1–2, 4–5 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Madigan in *Kahn*).

of the FDA's adverse event report database and Sanofi's internal pharmacovigilance database and his statistical analysis of Sanofi's clinical studies TAX 316 and TAX 301/GEICAM 9805—passed muster.[212] The Court also allowed Dr. Madigan to opine that a safety signal, defined as "a concern about an excess of adverse events compared to what would be expected to be associated with a product's use," emerged in 2000 and 2008, or "several years earlier" than 2015.[213]

The Court, however, precluded Dr. Madigan from opining that Taxotere actually causes PCIA (the second prong of general causation).[214] Dr. Madigan did not conduct a Bradford Hill analysis to demonstrate medical causation.[215] In *Kahn*, the Court also limited Dr. Madigan's testimony on Sanofi's internal database: Dr. Madigan could only refer to a reporting rate, not an incidence rate, of Taxotere patients who experienced permanent alopecia.[216] Last, Dr. Madigan was not permitted to testify about his meta-analysis of four observational studies because in practice he discouraged them in similar circumstances.[217]

**Ellen Feigal, M.D.** Dr. Ellen Feigal is an oncologist with experience in clinical trials, pharmacological product development, and pharmacovigilance.[218] The Court allowed Dr. Feigal to opine that Taxotere causes PCIA (the second prong of general causation).[219] To support her opinion,

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[212] Rec. Docs. 8094 at 8–10 (*Earnest*); 12098 at 6–14 (*Kahn*).
[213] Rec. Doc. 8094 at 10–11 (*Earnest*) (quoting Rec. Doc. 6144 at 4 (Mem. in Supp. of Defs.' Mot. to Exclude Expert Test. of Madigan)).
[214] Rec. Docs. 8094 at 6 (*Earnest*); 12098 at 4–6 (*Kahn*).
[215] Rec. Docs. 8094 at 5 (*Earnest*); 12098 at 4–6 (*Kahn*).
[216] Rec. Doc. 12098 at 10–11 (*Kahn*).
[217] Rec. Docs. 12098 at 12–13 (*Kahn*); 12403 at 3–4 (Order Denying Pl.'s Mot. to Recons. Order Regarding Madigan's Meta-Analysis of Observational Studies in *Kahn*).
[218] Rec. Doc. 11810 at 1–2 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Feigal in *Kahn*).
[219] Rec. Docs. 8094 at 5–8, 11–17 (*Earnest*); 11810 at 6 (*Kahn*).

Dr. Feigal relied on Dr. Madigan's statistical analysis, an adverse event report Sanofi prepared for FDA, medical literature, and Sanofi's clinical studies evaluating ongoing alopecia.[220]

The Court also permitted Dr. Feigal to offer general testimony on the following topics: the standard of care in the informed consent process, how pharmaceutical companies disseminate risk information, and treatment alternatives to Taxotere.[221] The Court, however, precluded Dr. Feigal from offering case-specific testimony.[222] Dr. Feigal, for example, could not opine on what a reasonable physician would have done with a warning about PCIA.[223] The Court reasoned that this testimony would imply that Sanofi's warning was inadequate when the Plaintiffs' treating physicians were available to testify about whether a different warning would have affected their prescribing decisions.[224]

**Linda Bosserman, M.D.** Dr. Linda Bosserman is a board-certified clinical oncologist who specializes in breast cancer.[225] The Court permitted Dr. Bosserman to offer general testimony on the following topics: medical guidelines and the standard of care for informed consent; the benefits and current use of online tools that predict the success of different chemotherapy treatments; how pharmaceutical companies disseminate risk information to physicians; the use of cooling caps to prevent hair loss; and the non-Taxotere treatment regimens available when the Plaintiff underwent treatment.[226]

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[220] Rec. Doc. 8094 at 5–8, 11–12 (*Earnest*).
[221] *Id.* at 17–19; Rec. Doc. 11810 at 5–6 (*Kahn*).
[222] Rec. Doc. 8094 at 18–19 (*Earnest*).
[223] Rec. Doc. 11810 at 6 (*Kahn*).
[224] Rec. Docs. 8094 at 18 (*Earnest*); 11810 at 5–6 (*Kahn*).

[225] Rec. Docs. 7807 at 1–2 (Order Granting in Part Defs.' Mot. to Exclude Expert Test. of Bosserman in *Earnest*); 12109 at 1–2 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Bosserman in *Kahn*).

[226] Rec. Docs. 7807 at 5–7 (*Earnest*); 12109 at 6–7, 9 (*Kahn*).

While the Court permitted Dr. Bosserman to provide general testimony on these topics, it precluded her from testifying about how they applied to the facts in a given Plaintiff's case. Accordingly, Dr. Bosserman could not testify about how a different warning from Sanofi would have affected the prescribing physician's treatment recommendation.[227] Dr. Bosserman also could not testify on Ms. Kahn's preferences and quality-of-life concerns when Ms. Kahn and her physicians were available to testify on those matters.[228] Dr. Bosserman also could not testify about how online predictive tools would apply in the Plaintiffs' cases.[229]

The Court also prohibited Dr. Bosserman from testifying on what Sanofi, the writers of the informed consent form for Ms. Kahn's clinical trial,[230] or Ms. Kahn's medical providers knew about the risk of PCIA associated with Taxotere.[231] The Court found that Dr. Bosserman offered no support for her opinions on knowledge and that, to the extent she relied on the opinions of Dr. Feigal, she did not validate Dr. Feigal's opinion.[232]

**Antonella Tosti, M.D.** The Court allowed Dr. Antonella Tosti, a dermatologist who treats women with hair loss, to testify as to specific causation—i.e., that Taxotere caused the specific bellwether Plaintiffs' PCIA.[233] To reach her opinions, Dr. Tosti relied on another physician to perform biopsies and a pathologist to study the tissue samples.[234] Dr. Tosti

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[227] Rec. Docs. 7807 at 4–5 (*Earnest*); 12109 at 5–6 (*Kahn*).
[228] Rec. Doc. 12109 at 6 (*Kahn*).
[229] Rec. Docs. 7807 at 6 (*Earnest*); 12109 at 7 (*Kahn*).
[230] Dr. Bosserman opined that the writers of the informed consent form, and thus the physicians and patients as well, were not informed about the PCIA risk from Sanofi's clinical trials. Rec. Doc. 12109 at 8 (*Kahn*).
[231] *Id.* at 9.
[232] *Id.*
[233] Rec. Docs. 8095 at 2, 4, 7–9 (Order Denying Defs.' Mot. to Exclude Expert Test. on Specific Causation in *Earnest*); 12401 at 2, 13 (Order Denying Defs.' Mot. to Exclude Test. of Tosti and Defs.' Mot. for Summ. J. on Specific Causation in *Kahn*).
[234] Rec. Docs. 8095 at 4–7 (*Earnest*); 12401 at 5–6 (*Kahn*).

then performed a differential diagnosis using the pathology results, further tests to rule out other causes, her classifications of alopecia, her experience, a review of the medical literature, and the work of the Plaintiffs' other experts.[235] The Court also allowed Dr. Tosti to testify that Ms. Kahn suffered from PCIA attributable to Taxotere rather than the other chemotherapy drugs Ms. Kahn received.[236]

**Laura Plunkett, PhD, DABT.** Dr. Laura Plunkett, a pharmacologist and toxicologist, was also put forth by the bellwether Plaintiffs to provide expert testimony.[237] In *Earnest*, the parties agreed that Dr. Plunkett would not offer opinions on causation, regulatory activities, Taxotere's efficacy, or Sanofi's promotional activities of Taxotere.[238] Dr. Plunkett was allowed to testify that PCIA differed from drug-induced alopecia ("DIA") in that DIA is not permanent.[239] Dr. Plunkett could also testify that Taxotere was associated with a greater risk of permanent alopecia compared to some other chemotherapy drugs.[240] The Court found her weight-of-the-evidence methodology passed muster.[241]

While the parties agreed that Dr. Plunkett could not provide causation testimony, the Court found that several of Dr. Plunkett's proposed areas of testimony overstepped this limitation. The Court did not permit Dr. Plunkett to testify that Taxotere carried an independent risk of permanent alopecia because she had not conducted a general causation analysis.[242] Further, Dr.

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[235] Rec. Docs. 8095 at 7–10 (*Earnest*); 12401 at 5–11 (*Kahn*).
[236] Rec. Doc. 12401 at 9–13 (*Kahn*).
[237] Rec. Docs. 8097 at 3 (Order Denying in Part & Deferring in Part Defs.' Mot. to Exclude Expert Test. of Plunkett in *Earnest*); 11823 at 1–2 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Plunkett in *Kahn*).
[238] Rec. Doc. 8097 at 3–4 (*Earnest*).
[239] Rec. Doc. 11823 at 6 (*Kahn*).
[240] Rec. Doc. 8097 at 3–6 (*Earnest*).
[241] Rec. Doc. 11823 at 7–8 (*Kahn*).
[242] *Id.* at 5.

Plunkett could not opine that Taxotere was a "substantial contributing factor" to permanent alopecia because the jury determines proximate causation.[243] Last, the Court did not allow Dr. Plunkett to opine that Taxotere was "more toxic" than Taxol. The Court reasoned that this opinion did not fit the facts of the case, and it could have led the jury to assume, without a sufficient basis, that Taxotere was more likely to cause permanent hair loss.[244]

After Ms. Earnest's trial but before Ms. Kahn's trial, Plaintiffs' regulatory expert Dr. David Kessler left the litigation.[245] Plaintiffs then had Dr. Plunkett submit a supplemental report containing regulatory opinions. Dr. Plunkett opined that Sanofi should have updated the Taxotere label before Ms. Kahn received her treatment in 2008.[246] The Court allowed Dr. Plunkett to offer her regulatory opinion but reiterated that Dr. Plunkett could not offer causation-based opinions.[247] The Court has allowed Sanofi to file additional challenges to the supplemental reports offered by Dr. Plunkett for the renewed *Earnest* trial and her preservation deposition, which will be provided to the relevant courts.

**David B. Ross, M.D., PhD, MBI.** Ms. Kahn also designated, but did not call, Dr. David Ross as a regulatory expert to replace Dr. Kessler.[248] Dr. Ross worked for FDA as a medical officer from 1996 to 2006.[249] The Court permitted Dr. Ross to provide his FDA regulatory and safety signal opinions based on Dr. Madigan's statistical analysis and the methodology Dr. Ross would use at

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[243] *Id.* at 5–6.
[244] Rec. Docs. 8097 at 6 (*Earnest*); 11823 at 4–5 (*Kahn*).
[245] *See* Rec. Doc. 12173 (Order Denying Defs.' Mot. to Exclude Expert Test. of Kessler as Moot in *Kahn*).
[246] Rec. Doc. 13131 at 2, 4 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Suppl. Op. of Plunkett in *Kahn*).
[247] Rec. Doc. 13131 at 5–6 (*Kahn*).
[248] Rec. Doc. 13063 at 1–2 (Order Denying Defs.' Mot. to Exclude Expert Test. of Ross in *Kahn*).
[249] *Id.* at 2.

FDA.[250]

**b) Sanofi's Experts**

The Court has also assessed the opinions of Sanofi's experts under Rule 702 before both bellwether trials. At both trials, Sanofi called only Dr. John Glaspy to testify as an expert.

**Jerry Shapiro, M.D., and Chandra Smart, M.D.** Before the *Earnest* bellwether trial, Sanofi designated Dr. Jerry Shapiro, a dermatologist, and Dr. Chandra Smart, a dermatopathologist, to offer opinions on stem cell staining.[251] Stem cell staining was at issue because Plaintiff's general causation expert had opined that PCIA may result due to irreversible damage to stem cells.[252] Further, Plaintiff's dermapathology expert conducted Ki-67 and cytokeratin 15 stem cell staining on Plaintiff's scalp biopsies.[253] The results of the test were positive, evincing that Plaintiff's stem cells were present and proliferating.[254]

The Court agreed with Sanofi that stem cell staining was relevant to disprove Plaintiff's theory that chemotherapy damaged Ms. Earnest's stem cells and caused her persistent alopecia.[255] The Court rejected Plaintiff's argument that Dr. Shapiro and Dr. Smart were not qualified to testify because they were not "stem cell experts."[256] Specifically, the Court noted that Dr. Shapiro had decades of experience as a dermatologist and, in that role, had gained an understanding of stem cell testing.[257] Similarly, the Court found that although Dr. Smart "may not be a 'stem cell expert,' she [was] qualified to read

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[250] *Id.* at 5–6.
[251] Rec. Doc. 8133 (Order Denying Pl.'s Mot. to Exclude Dr. Shapiro's and Dr. Smart's Stem Cell Ops. in *Earnest*).
[252] *Id.* at 5–6.
[253] *Id.* at 6.
[254] *Id.* at 7.
[255] *Id.* at 5–7.
[256] *Id.* at 3.
[257] *Id.* at 4–5.

and understand the results of Plaintiff's stem cell stains."[258] The Court, however, did not permit either expert to refer to the stem cell study conducted for Ms. Earnest as a "failed study" and limited Dr. Shapiro and Dr. Smart to testimony addressing Ms. Earnest's slides only.[259] The Court also explained that it would limit Dr. Shapiro and Dr. Smart's testimony as appropriate if it became unnecessarily cumulative.[260]

In *Kahn*, Sanofi designated only Dr. Shapiro to opine on stem cell staining.[261] The Court reiterated that Dr. Shapiro had sufficient experience with hair disorders to testify on stem cell staining, but again excluded Dr. Shapiro from referring to the stem cell study as a "failed study."[262]

**John Glaspy, M.D.** Sanofi sought to introduce the testimony of oncologist Dr. John Glaspy to testify on the common types and causes of alopecia he observes and treats in his breast cancer patients.[263] The Court allowed Dr. Glaspy to opine generally on the types and causes of alopecia, as well as on FDA-related topics, including the process of clinical trials, how the "new drug application" process generally operates, and how underlying data from Taxotere clinical trials are submitted to FDA.[264] Based on his experience as an oncologist, Dr. Glaspy was also permitted to opine on the Taxotere label; common sentiments breast cancer patients may have and express about treatment and survival; breast cancer survival rates and how they are affected by various chemotherapy regimens; the alternatives to Taxotere-containing regimens and the absence of any guarantees in the oncological setting; and the

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[258] *Id.* at 5. The Court also noted that an expert is not strictly confined to his or her area of practice but may testify "concerning related applications." *Id.* at 4–5.
[259] *Id.* at 8.
[260] *Id.*
[261] Rec. Doc. 12402 (Order Denying Pl.'s Mot. to Exclude Dr. Shapiro's Ops. in *Kahn*).
[262] *Id.* at 3–5.
[263] Rec. Doc. 11780 at 4–5 (Order Denying Pl.'s Mot to Exclude Test. of John Glaspy, M.D. in *Kahn*).
[264] *Id.* at 4–7.

side effects of chemotherapy drugs, how clinicians weigh side effects, and how and what side effects are communicated to patients.[265]

Before *Earnest*, the Court also permitted Dr. Glaspy to offer causation opinions, relying in part on Dr. Glaspy's review of the Sanofi-sponsored, ten-year multi-center Phase III randomized clinical trial—TAX 316. The Fifth Circuit later reversed and remanded Ms. Earnest's case for a new trial, in part because of Dr. Glaspy's reliance on Dr. Kopreski's testimony on the TAX 316 clinical data without independently reviewing his results. *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Earnest)*, 26 F.3d at 267. During *Kahn*, Dr. Glaspy did not offer any opinions that relied on Dr. Kopreski's testimony about the TAX 316 study.

**Janet Arrowsmith, M.D.** Dr. Janet Arrowsmith is a doctor in internal medicine, an epidemiologist, and a former FDA employee. In both bellwether cases, the Court permitted Dr. Arrowsmith to testify generally about alternative causes of alopecia, as well as opinions on the following topics: (1) her regulatory opinions, including that reasonable evidence of causal association means a signal is confirmed and "is not merely a 'weak' or 'potential' signal" referred to further evaluation; (2) how "medical and regulatory judgment" is necessary to define a term when statutory definitions are not available; and (3) why she believes permanent alopecia was not appropriate in the "Warning and Precautions" section of the Taxotere label.[266]

In *Kahn*, this Court's denied Plaintiff's request to prohibit Dr. Arrowsmith from testifying about the alleged statistical significance of ongoing alopecia based on the TAX 316 data, including her opinions that relied on the

[265] *Id.* at 6–12.
[266] Rec. Doc. 11781 at 5–8 (Order Denying Pl.'s Mot. to Exclude Test. of Dr. Janet Arrowsmith in *Kahn*).

testimony of Dr. Kopreski.[267] Like Dr. Glaspy's testimony, this portion of her testimony is therefore implicated by the Fifth Circuit's decision *In re Taxotere (Docetaxel) Products Liability Litigation (Earnest)*, 26 F.3d at 267.

**L.J. Wei, PhD.** Dr. Lee-Jen Wei is a biostatistician and processor of biostatistics.[268] Sanofi designated Dr. Wei to opine on the TAX 316 clinical trial before *Kahn,* including the following opinions: (1) the TAX 316 and TAX 301 studies do not provide evidence of a safety signal of a new or unexpected risk of permanent alopecia compared to alternative chemotherapies; (2) Dr. Madigan's analyses suffer from serious and well-known limitations, rendering them of little or no value in determining whether there is reliable statistical evidence that Taxotere is associated with an increased risk of permanent alopecia; (3) the majority of patients with ongoing alopecia in the TAX 316 study were followed for their alopecia for less than six months, making it impossible to say those patients experienced "irreversible" alopecia; and (4) Dr. Madigan's analyses relating to the Sanofi 2012 Health Canada submission are arbitrary and misleading.[269]

Although Ms. Kahn challenged Dr. Wei's opinions on the TAX 316 clinical trial, the Court found that these opinions were based on sufficient data under Rule 702.[270] Ms. Kahn also challenged Dr. Wei's opinions because Dr. Wei relied on other statisticians from his company, Blue Null, to perform calculations for his report without disclosing this fact in his report.[271] While the Court found the non-disclosure was improper, it reasoned that Dr. Wei's reliance on his colleagues was reasonable under Rule 703, and Ms. Kahn was

[267] *Id.* at 6–7.
[268] Rec. Doc. 12107 (Order Denying Pl.'s Mot. to Exclude Test. of Professor L.J. Wei in *Kahn*).
[269] Rec. Doc. 11103 at 2–3 (Defs.' Opp. to Pl.'s Mot. to Exclude Expert Test. of Dr. L.J. Wei in *Kahn*).
[270] Rec. Doc. 12107 at 4–6 (*Kahn*)
[271] *Id.* at 5–6.

not prejudiced because Dr. Wei disclosed his reliance on others at his deposition.[272]

**Gerald Miletello, M.D.** Dr. Gerald Miletello is an oncologist with years of experience treating breast cancer and other cancers.[273] In *Kahn*, the Court permitted Dr. Miletello to offer his opinion on alternative causes of alopecia, including chemotherapy drugs other than Taxotere, the aging process, and certain endocrine-based therapies.[274] Dr. Miletello could also offer opinions on the efficacy of taxane-containing regimens; his personal prescribing preferences, including his preference for Taxotere in Ms. Kahn's situation; the risk-benefit analysis he employs in making his prescribing decisions; and his thoughts of the Taxotere label from his perspective as an oncologist.[275] The Court, however, did not permit Dr. Miletello to opine on whether he believed the Taxotere label complied with FDA regulations.[276] Nor could Dr. Miletello offer opinions duplicative of Dr. Glaspy's opinions.[277] The Court also noted that, to the extent Dr. Miletello contradicted his prior testimony about the similar efficacy of Taxotere and Taxol, "Plaintiff [could] illuminate this on cross-examination."[278]

**Mamina Turegano, M.D.** Sanofi designated Dr. Mamina Turegano as a specific causation expert to testify on the association of various anti-cancer agents and permanent hair loss.[279] The Court found that Dr. Turegano employed a reliable methodology in developing her opinions and permitted Dr.

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[272] *Id.*
[273] Rec. Doc. 11804 at 1 (Order Denying Pl.'s Mot. to Exclude Causation Test. of Dr. Gerald Miltello in *Kahn*).
[274] *Id.* at 4–5.
[275] *Id.* at 5–6.
[276] *Id.* at 6.
[277] *Id.* at 5.
[278] *Id.*
[279] Rec. Doc. 12160 at 3–5 (Order Denying Pl.'s Mot. to Exclude Test. of Dr. Mamina Turegano in *Kahn*).

Turegano to opine on alternative causes of Ms. Kahn's hair loss.[280]

Plaintiff argued that Dr. Turegano did not properly disclose her opinions under Federal Rule of Civil Procedure 26(a)(2)(B) because she did not provide an opinion in her report "as to whether she considered or ruled out Taxotere-containing regimens as a cause of Plaintiff's alleged permanent hair loss."[281] The Court disagreed and found that Dr. Turegano's report compiled with Rule 26, as it provided a complete statement of her opinions, the reasons for them, and the facts and data she considered.[282] The Court noted that "to the extent [Dr. Turegano] failed to spell out the steps of her differential diagnosis," Ms. Kahn could address this during cross examination.[283]

**Ellen T. Chang, Sc.D.** Dr. Ellen Chang is an epidemiologist specializing in cancer. Before trial, Ms. Kahn moved to exclude Dr. Chang's testimony on (1) the TAX 316 clinical trial, (2) whether other medications can cause PCIA, and (3) the "forms and risk factors" of alopecia.[284] The Court permitted Dr. Chang to testify that persistent alopecia is associated with other medications, as well as to the general "forms and risk factors" of alopecia.[285] But the Court precluded Dr. Chang from testifying that medications that Plaintiff did not take could cause PCIA because they were irrelevant to the case.[286]

Dr. Chang filed a supplemental report in *Kahn*, which offered additional opinions in response to new labeling opinions offered by Dr. Ross and Dr. Plunkett. Ms. Kahn sought to exclude Dr. Chang's opinions as untimely, asserting that Dr. Chang's new opinions should have been included in her

[280] *Id.* at 5–6.
[281] *Id.* at 5.
[282] *Id.* at 5–6.
[283] *Id.* at 6.
[284] Rec. Doc. 10934 at 1–2 (Pl.'s Mot. to Exclude Certain Ops. of Ellen T. Chang, Sc.D in *Kahn*).
[285] Rec. Doc. 12108 at 4–7 (Order Denying Pl.'s Mot. to Exclude Certain Ops. of Ellen T. Chang, Sc.D in *Kahn*).
[286] *Id.* at 5–6.

original report. The Court, however, found Dr. Chang's supplemental report was "an appropriate rebuttal to the opinions of Dr. Ross and Dr. Plunkett" and allowed Dr. Chang to testify to her supplemental report.[287]

**Azael Freites-Martinez, M.D.** In *Kahn*, Sanofi sought to introduce the testimony of Dr. Azael Freites-Martinez—a dermatologist who specializes in chemotherapy regimens and persistent alopecia.[288] The Court found that Dr. Freites-Martinez was qualified to testify regarding specific causation and Ms. Kahn's hair loss.[289] The Court noted that Dr. Freites-Martinez "need not be licensed in the United States to opine on Ms. Kahn's hair loss," and that it was "inconsequential" to Dr. Freites-Martinez's specific causation opinion that he did not examine Ms. Kahn in person.[290]

### 10. Motions in Limine

In advance of the *Earnest* and *Kahn* trials, Sanofi filed 57 motions in limine and Plaintiffs filed 38. While most are necessarily influenced by case-specific facts and jurisdiction-specific law, the Court nevertheless provides a listing of these motions in appended Exhibit A which reflects the motions in limine for both trials, and indication of the filing party, and the rulings, for the benefit of the remand courts should they find such rulings instructive.

## II. NATURE AND EXPECTED DURATION OF FURTHER PROCEEDINGS

Because all general fact and expert discovery has been completed in the MDL, the courts receiving these cases need not be concerned with facilitating general expert, corporate, and third-party discovery. Case-specific discovery

[287] Rec. Doc. 13072 at 4–6 (Order Denying Pl.'s Mot. to Strike the Untimely Report of Ellen Chang, ScD in *Kahn*).
[288] Rec. Doc. 12404 (Order Denying Pl.'s Mot. to Exclude Test. of Azael Freites-Martinez in *Kahn*).
[289] *Id.* at 4–8.
[290] *Id.* at 6–7.

and trial preparation, however, will be determined on remand or transfer. As noted in the Wave Work Up section of this Order, the Wave 1 Plaintiffs have undergone limited case work-up. Specifically, the parties have conducted records collection and completed depositions of Plaintiff. Some parties have also completed depositions of Plaintiff's prescribing physician, a sales representative, and, where applicable, a treating physician. Receiving courts can anticipate additional case-specific fact discovery, including Plaintiff's spouse, if any, friends and family, and healthcare providers. In addition, this Court did not enter any inventory-wide medical diagnosis order. As a result, case-specific expert discovery likely will require dermatology experts to corroborate each Plaintiff's claim that she experienced PCIA caused by Taxotere. In each of the trial cases, this has entailed the taking of scalp biopsies and certain sharing provisions for reading such pathology by each side's experts.

Receiving courts should also expect to address case-specific motions for summary judgment on dispositive issues, such as the statute of limitations and warnings causation. Additional motion practice will likely include case-specific expert challenges under Federal Rule of Evidence 702. Before trial, receiving courts may also anticipate ruling on case-specific motions in limine and objections to case-specific deposition designations and exhibits.

## III. COMMON BENEFIT WORK

Attorneys in this MDL—in particular, the PEC, PSC, Plaintiffs' Settlement Committee, and certain subcommittee contributing counsel—have expended significant resources and made substantial common-benefit contributions to this MDL on behalf of all Plaintiffs.[291] All counsel on the PSC

[291] *See* Pretrial Orders Nos. 2, 6, 8, 19, 20, 31, 75, 89, 93 (Docs. 104, 133, 156, 262, 265, 305, 1507, 5377, 6018).

or authorized by the PSC to do common benefit work are skilled, experienced and capable professionals. Therefore, these attorneys should be entitled to the fair and equitable assessment of any recovery for the services performed and expenses incurred by attorneys acting for MDL administration and common benefit of all plaintiffs in this complex litigation.[292]

"The effect of an order remanding a case to the transferor court for trial is to divest the transferee court of jurisdiction in the case and to vest the transferor court with jurisdiction."[293] "The Panel's power to sever and remand a portion of an action is limited to entire claims. The Panel cannot remand only part of a claim or only certain factual issues."[294] The award of attorney's fees, nevertheless, is a "collateral matter over which a court normally retains jurisdiction even after being divested of jurisdiction on the merits."[295]

Accordingly, because the fees awarded to the MDL attorneys for the common benefit of all Plaintiffs is a collateral issue separate from the merits of this case, the Court suggests that it retains jurisdiction to consider the fair and equitable assessment of any potential recovery for the services performed and expenses incurred by attorneys acting for administration and common benefit of all MDL plaintiffs.

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[292] *See* Pretrial Order 19 (Doc. 262); Order and Reasons of November 15, 2022 modifying the common benefit holdback percentages for fees (to 15%) and expenses (to 4.75%) of any recovery (Doc. 15143); *In re* FedEx Ground Package Sys., Inc. Employment Practices Litig., No. 3:05-MD-527 RM, 2010 WL 785279, at *5–6 (N.D. Ind. Mar. 2, 2010).

[293] *Id.* (citing David F. Herr, Multidistrict Litigation Manual, § 10:5 (2005)).

[294] *Id.* (citation omitted).

[295] *Id. See also In re* Zyprexa Prods. Liab. Litig., 467 F. Supp. 2d 256, 274 (E.D.N.Y. 2006) (citations omitted); In re Zyprexa Prods. Liab. Litig., 594 F.3d 113, 2010 WL 367556, *10 (2d Cir. 2010) (stating that order imposing an assessment to create a fund that could be used to compensate attorneys who demonstrate that their efforts conferred a benefit on the Plaintiffs generally is "even less related to the ultimate merits than orders awarding attorney's fees, which are collateral matters over which a court retains jurisdiction even if it ultimately is determined to lack subject matter jurisdiction.").

New Orleans, Louisiana, this 11th day of May, 2023.

**JANE TRICHE MILAZZO**
**UNITED STATES DISTRICT JUDGE**

**EXHIBIT A**

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 7643 | Sanofi's Corporate Character and Good Acts | Plaintiff | Deferred due to vagueness (Rec. Doc. 8206) |
| 7644 | Plaintiff's Experts Have Not Publicized/Published or Submitted Their Opinions to the FDA or Any Other Organizations | Plaintiff | Denied (Rec. Doc. 8206) |
| 7645 | "Stem Cell" Staining | Plaintiff | Dismissed as moot (Rec. Doc. 8206) |
| 7646 | Plaintiff Counsel Advertisements | Plaintiff | Granted in part, denied in part (Rec. Doc. 8206) |
| 7647 | Unrelated Medical Conditions, Familial Medical History of Cancer, and Unrelated Medication Usage | Plaintiff | Granted in part, denied in part (Rec. Doc. 8201) |
| 7648 | Discussing Certain Matters in the Presence of the Jury or Potential Jurors | Plaintiff | Granted in part, denied in part (Rec. Doc. 8206) |
| 7649 | Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy | Plaintiff | Granted in part, denied in part (Rec. Doc. 8201) |
| 7650 | Healthcare Costs and Insurance as a Collateral Source | Plaintiff | Granted in part, denied in part (Rec. Doc. 8206) |
| 7651 | Other Chemotherapy Medications or Medical Conditions That Purportedly Cause Permanent Hair Loss | Plaintiff | Granted in part, denied in part (Rec. Doc. 8198) |
| 7652 | Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts | Plaintiff | Granted (Rec. Doc. 8198) |
| 7653 | Dr. Carinder is Responsible for Plaintiff's Condition | Plaintiff | Granted in part, denied in part (Rec. Doc. 8198 |
| 7657 | What Treatment Dr. Carinder Would Prescribe to Plaintiff Today | Defendant | Granted (Rec. Doc. 8206) |

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 7657 | What Plaintiff Would Have Done Differently if She had been Given Different Risk Information by Her Prescribing Oncologist | Defendant | Denied (Rec. Doc. 8206) |
| 7657 | Sanofi Promotional and/or Marketing Materials Not Possessed or Relied On by Plaintiff or Her Prescribing Physician | Defendant | Denied (Rec. Doc. 8201) |
| 7657 | Non-Expert Causation Testimony | Defendant | Deferred (Rec. Doc. 8206) |
| 7657 | Plaintiff's Motive and/or Mental State | Defendant | Granted in part, deferred in part (Rec. Doc. 8206) |
| 7657 | Sanofi Sales Representative | Defendant | Denied (Rec. Doc. 8201) |
| 7658 | Correspondence Between DDMAC and Sanofi | Defendant | Granted (Rec. Doc. 8201) |
| 7659 | FDA Approval | Plaintiff | Granted in part, denied in part, deferred in part (Rec. Doc. 8201) |
| 7660 | Taxotere Has Saved Lives | Plaintiff | Granted in part, denied in part (Rec. Doc. 8198) |
| 7661 | Other Individuals' Personal Use of Taxotere and Personal Experience With Cancer | Plaintiff | Deferred (Rec. Doc. 8206) |
| 7662 | Sanofi as a "French" or "Foreign" Company | Defendant | Granted in part, denied in part (Rec. Doc. 8206) |
| 7664 | Alleged "High Toxicity" of Taxotere Causes or Is Associated With Alopecia | Defendant | Dismissed as moot (Rec. Doc. 8206) |
| 7666 | Foreign Labeling and Regulatory Actions | Defendant | Granted in part, denied in part (Rec. Doc. 8201) |
| 7668 | "Ongoing Alopecia" Data Observed in the Tax316 and GEICAM 9805 Clinical Trials Represents Evidence of "Persistent," "Permanent," or "Irreversible" Alopecia | Defendant | Denied (9/5/2019 Hearing Transcript, 110:23-111:3) |
| 7670 | Shirley Ledlie and Any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members | Defendant | Granted (Rec. Doc. 8201) |

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 7671 | Company Conduct That Post-Dates Plaintiff's Chemotherapy Treatment | Defendant | Granted (Rec. Doc. 8201) |
| 7673 | FDA's January 2011 Warning Letter and Corresponding 483 Inspection | Defendant | Granted (Rec. Doc. 8216) |
| 7720 | Purported Moral Or Ethical Duties of Pharmaceutical Drug Manufacturers | Defendant | Granted (Rec. Doc. 8206) |
| 7720 | Purported Legal Duties and Conclusions | Defendant | Deferred (Rec. Doc. 8206) |
| 7720 | Other Lawsuits, Claims, or Investigations Against Defendants and/or Other Sanofi Entities | Defendant | Granted in part, denied in part (Rec. Doc. 8206) |
| 7720 | Complaints and Lawsuits Against Other Manufacturers of Docetaxel | Defendant | Granted in part (Rec. Doc. 8206) |
| 7720 | Adverse Event Reports or Other Complaints Involving Patients Other Than Plaintiff | Defendant | Deferred (Rec. Doc. 8216) |
| 7720 | Presence, Absence, or Identity of Defendants' Corporate Representative at Trial | Defendant | Granted (Rec. Doc. 8206) |
| 7720 | Defendants' Executive and/or Employee Compensation | Defendant | Deferred (Rec. Doc. 8206) |
| 7720 | Cost of Taxotere or Prescription Drug Pricing Generally | Defendant | Granted (Rec. Doc. 8206) |
| 7720 | Defendants' Corporate Finances or Employment Decisions | Defendant | Deferred (Rec. Doc. 8206) |
| 7720 | Expert Opinions That Exceed the Scope of Plaintiff's Experts' Rule 26 Expert Disclosures | Defendant | Deferred (Rec. Doc. 8206) |
| 7720 | Defendants' Corporate Intent, Motives, or State of Mind | Defendant | Granted in part, denied in part (Rec. Doc. 8206) |
| 7720 | Defendants' Corporate Integrity Agreements, Government Investigations or Settlements, and Any Other Alleged "Bad Acts" Unrelated to Taxotere | Defendant | Granted (Rec. Doc. 8206) |
| 7720 | Specific Litigation Conduct | Defendant | Granted (Rec. Doc. 8206) |
| 7720 | Alleged Fraud on the FDA | Defendant | Deferred (Rec. Doc. 8206) |

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 12888 | Healthcare Costs and Insurance as a Collateral Source | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12889 | "Stem Cell" Staining | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12890 | Taxotere Has Saved Lives | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12891 | Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12892 | Sanofi's Corporate Character and Good Acts | Plaintiff | Granted in part, deferred in part (Rec. Doc. 13260) |
| 12893 | Defense Counsel Commenting on or Discussing Certain Matters in the Presence of the Jury or Potential Jurors | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12894 | American Cancer Society Breast Cancer Dictionary | Plaintiff | Deferred (Rec. Doc. 13260) |
| 12895 | Low Quality Photographs | Plaintiff | Deferred (Rec. Doc. 13260) |
| 12896 | Prejudicial Litigation Conduct | Plaintiff | Deferred (Rec. Doc. 13260) |
| 12897 | Plaintiff's Counsel's Advertisements | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12898 | Personal Use of Taxotere or Other Cancer Drugs by Any Defendant Employee Witness, Expert Witness, Attorney, and/or Family Member, or Their Personal Experiences With Cancer | Plaintiff | Deferred (Rec. Doc. 13260) |
| 12899 | Taxotere Has Been Proven Superior to Taxol – Or Any Drug Other Than 5-FU – Or That Taxotere Gave Plaintiff the "Best Chance" of Surviving Cancer, Or That Taxotere Gave Her the "Best Chance" for Preventing Her Cancer From Returning | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12900 | Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts | Plaintiff | Granted (Rec. Doc. 13260) |

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 12901 | Unrelated Medical Conditions, Unrelated Familial Medical History, and Unrelated Medication Usage | Plaintiff | Granted in part, denied in part, deferred in part (Rec. Doc. 13260) |
| 12902 | Improper Arguments or Suggestions Regarding FDA Approval | Plaintiff | Conditionally granted (Rec. Doc. 13260) |
| 12903 | Unsupported Statements From Counsel in Opening and Closing Statements | Plaintiff | Granted (Rec. Doc. 13260) |
| 12905 | Comparative Fault of her Treating Physicians and Misuse of Taxotere | Plaintiff | Granted in part, denied in part (Rec. Doc. 13260) |
| 12907 | Online Advocacy | Plaintiff | Denied (Rec. Doc. 13260) |
| 12909 | Use of Unreliable Evidence to Support Claims of Alternative Causation and/or Questioning Which Misconstrues the Applicable Burden | Plaintiff | Denied (Rec. Doc. 13260) |
| 12968 | Purported Moral or Ethical Duties of Pharmaceutical Drug Manufacturers | Defendant | Granted (Rec. Doc. 13260) |
| 12968 | Purported Legal Duties and Conclusions | Defendant | Deferred (Rec. Doc. 13260) |
| 12968 | Other Lawsuits, Claims, or Investigations Against Defendants and/or Other Sanofi Entities | Defendant | Granted in part, denied in part (Rec. Doc. 13260) |
| 12968 | Complaints and Lawsuits Against Other Manufacturers of Docetaxel | Defendant | Granted in part (Rec. Doc. 13260) |
| 12968 | Adverse Event Reports or Other Complaints Involving Patients Other Than Plaintiff | Defendant | Deferred (Rec. Doc. 13260) |
| 12968 | Presence, Absence, or Identity of Defendants' Corporate Representative at Trial | Defendant | Granted (Rec. Doc. 13260) |
| 12968 | Defendants' Executive and/or Employee Compensation | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Cost of Taxotere and Prescription Drug Pricing Generally | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Defendants' Corporate Finances or Employment Decisions | Defendant | Conditionally granted (Rec. Doc. 13260) |

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 12968 | Expert Opinions that Have Been Disclaimed and/or that Exceed the Scope of Plaintiff's Experts' Rule 26 Disclosures and Deposition Testimony | Defendant | Denied (Rec. Doc. 13260) |
| 12968 | Defendants' Corporate Intent, Motives, or State Of Mind | Defendant | Granted in part, denied in part (Rec. Doc. 13260) |
| 12968 | Defendants' Corporate Integrity Agreements, Government Investigations or Settlements, or Any Other Alleged "Bad Acts" Unrelated to Taxotere | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Specific Litigation Conduct | Defendant | Granted (Rec. Doc. 13260) |
| 12968 | Alleged Fraud on the FDA | Defendant | Deferred (Rec. Doc. 13260) |
| 12968 | Reference to PCIA as "Common" | Defendant | Denied (Rec. Doc. 13260) |
| 12968 | What Ms. Kahn Would Have Done Differently if She Had Been Given Different Risk Information by Her Prescribing Oncologist | Defendant | Deferred (Rec. Doc. 13260) |
| 12968 | Sanofi Promotional and/or Marketing Materials Not Possessed or Relied On by Ms. Kahn or Her Prescribing Physician | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Non-Expert Causation Testimony | Defendant | Deferred (Rec. Doc. 13260) |
| 12968 | Plaintiff's Motive and/or Mental State | Defendant | Granted in part, deferred in part (Rec. Doc. 13260) |
| 12968 | Sanofi Sales Representatives, and to Exclude Sales Representative Witness Testimony | Defendant | Denied (Rec. Doc. 13260) |
| 12968 | Correspondence Between DDMAC and Sanofi | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Referring to Sanofi as a "French" or "Foreign" Company | Defendant | Granted in part, denied in part (Rec. Doc. 13260) |
| 12968 | FAERS Signal Evaluation | Defendant | Denied (Rec. Doc. 13260) |
| 12968 | Foreign Labeling and Regulatory Actions | Defendant | Granted in part, denied in part (Rec. Doc. 13260) |

| REC. DOC. | TOPIC | FILED BY | RULING |
|---|---|---|---|
| 12968 | "Ongoing Alopecia" Data Observed in the TAX316 and GEICAM 9805 Clinical Trials Represents Evidence of "Persistent," "Permanent," or "Irreversible" Alopecia | Defendant | Denied (Rec. Doc. 13260) |
| 12968 | Shirley Ledlie, any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members, Facebook Voices Page, And Intouch Solutions | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Company Conduct that Post-Dates Plaintiff's Chemotherapy Treatment | Defendant | Granted in part, deferred in part (Rec. Doc. 13260) |
| 12968 | FDA's January 2011 Warning Letter and Corresponding 483 Inspection | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Plaintiff's Actinic Keratosis was Caused By Taxotere or PCIA, or Claiming Damages Therefor | Defendant | Granted in part, denied in part (Rec. Doc. 13260) |
| 12968 | Use of Cold Caps | Defendant | Granted (Rec. Doc. 13260) |
| 12968 | Canadian Informed Consent | Defendant | Denied (Rec. Doc. 13260) |
| 12968 | Dr. Kessler or his Role in the U.S. Government's Covid-19 Response Team | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Duplicative Expert Testimony | Defendant | Granted (Rec. Doc. 13260) |
| 12968 | Punitive Damages Evidence | Defendant | Conditionally granted (Rec. Doc. 13260) |
| 12968 | Dear Health Care Provider Letters | Defendant | Denied (Rec. Doc. 13260) |
| 13422 | Alternative Causation | Plaintiff | Denied (Rec. Doc. 13433) |

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

| | | |
|---|---|---|
| IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION | : | MDL NO. 2740 |
| | : | SECTION "H" (5) |
| THIS DOCUMENT RELATES TO ALL CASES | : | HON. JANE TRICHE MILAZZO |

**SECOND AMENDED MASTER LONG FORM COMPLAINT AND DEMAND FOR JURY TRIAL**

1. COME NOW, Plaintiffs, through the Plaintiffs' Steering Committee, who submit this Second Amended Master Long Form Complaint and Demand for Jury Trial ("Second Amended Master Complaint"). This Second Amended Master Complaint sets forth common allegations of Plaintiffs who were injured as a result of their exposure to brand-name drug products Taxotere, Docefrez, Docetaxel Injection Concentrate, and Docetaxel Injection that were approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). These brand-name drug sponsors, manufacturers, labelers, and distributors are Defendants Sanofi S.A., Aventis Pharma S.A., Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, Sandoz Inc., Accord Healthcare, Inc., McKesson Corporation d/b/a McKesson Packaging ("McKesson"), Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc., Hospira, Inc., Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories Ltd., Pfizer Inc., Actavis LLC f/k/a Actavis Inc., Actavis Pharma, Inc., and Sagent Pharmaceuticals, Inc. (collectively "Defendants") for damages and such other relief deemed just and proper.

2. This Second Amended Master Complaint is intended to achieve efficiency and economy by presenting certain common allegations and common questions of fact and law that generally pertain to Plaintiffs adopting this Complaint. Plaintiffs plead all Counts of this Second

Amended Master Complaint and Jury Demand in the broadest sense, pursuant to all applicable laws and pursuant to choice of law principles, including the law of the each Plaintiff's home state.

3. This Second Amended Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court. It is anticipated that individual Plaintiffs will adopt this Second Amended Master Complaint and selected causes of action herein through the use of a separate Short Form Complaint. Any individual facts, jurisdictional allegations, additional legal claims and/or requests for relief of individual Plaintiffs may be set forth as necessary in the Short Form Complaint filed by the respective Plaintiffs. This Second Amended Master Complaint does not constitute a waiver or dismissal of any claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery and trials proceed.

## INTRODUCTION

4. Taxotere is a chemotherapy drug administered to many who suffer primarily from breast cancer. Brand-name drug sponsors, manufacturers, labelers, and distributors of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, have known for years that these drugs cause permanent hair loss, a now well-documented side effect that for years has been publicized in numerous scientific studies, articles, and presentations. Despite this, these brand-name entities failed to warn patients and healthcare providers of the risk of permanent hair loss and report this risk to the Food and Drug Administration ("FDA"). Instead, Defendants hid this devastating side effect. In fact, some brand-name entities still fail to disclose that permanent hair loss is a common side effect.

5. Plaintiffs are women who were diagnosed with breast cancer, underwent chemotherapy using Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and/or

Docefrez,, and now suffer from permanent hair loss, a side effect for which they were not warned and were wholly unprepared. Had Plaintiffs and Plaintiffs' healthcare providers known that permanent hair loss could result, they would have selected a different treatment option—effective alternatives to these drugs that do not lead to this devastating side effect are used regularly.

6. As a result of this undisclosed side effect, Plaintiffs have struggled to return to normalcy, even after surviving cancer because an integral element of their identities, their hair, never returned. Plaintiffs are stigmatized with the universal cancer signifier—baldness—long after they underwent cancer treatment, and their hair loss acts as a permanent reminder that they are cancer victims. This permanent change has altered Plaintiffs' self-image, negatively impacted their relationships, and others' perceptions of them, leading to social isolation and depression even long after fighting cancer.

7. Defendants failed, and some still fail, to warn that permanent or irreversible hair loss is a common side effect of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, and Plaintiffs have been unable to weigh this devastating possibility when deciding among treatment options. Plaintiffs seek recovery for their mental and physical suffering stemming from permanent or irreversible hair loss.

## THE PARTIES

### A. Plaintiffs

8. This Second Amended Master Complaint is filed on behalf of all Individual Injured Plaintiffs ("Plaintiffs") whose claims are subsumed within MDL No. 2740. Plaintiffs in these individual actions have suffered personal injuries as a result of the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez. In addition, and where applicable, this Second Amended Master Complaint is also filed on behalf of Plaintiffs' spouses, children, parents, decedents, wards and/or heirs, all represented by Plaintiffs' counsel.

9. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

10. Plaintiffs file these lawsuits within the applicable statute of limitations period of first suspecting that these drugs caused the appreciable harm they sustained. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of their injuries as the cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did they have reason to suspect that they had been injured, the cause of their injuries, or the tortious nature of the conduct causing their injuries until a date prior to the filing of these actions, which is less than the applicable limitations period for filing suit.

11. Additionally, Plaintiffs were prevented from discovering this information at an earlier date because: (1) Defendants misrepresented to the public, the FDA, and the medical profession that Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, are free from permanent side effects; (2) Defendants failed to disclose to the public, the FDA, and the medical profession their knowledge of the risk of permanent side effects; and (3) Defendants fraudulently concealed facts and information that could have led Plaintiffs to discover the liability of the Defendants.

**B. Sanofi-Related Entitites**

12. Defendant Sanofi S.A. f/k/a Sanofi Aventis S.A. is the owner and operator of a multinational vertically integrated pharmaceutical company organized and existing under the laws of France with a principal place of business at 54 Rue La Boétie, 75008 Paris, France. Sanofi S.A. formed in 2004 after Sanofi-Synthélabo acquired Aventis Group, including subsidiary Defendant

Aventis Pharma, S.A. Sanofi S.A. is engaged in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere. American Depositary Receipts for Sanofi SA are traded on the New York Stock Exchange. It is the only publicly traded company among the various Sanofi entities named as defendants in the case.

13. Defendant Aventis Pharma S.A. is a corporation organized and existing under the laws of France with a principal place of business at 20 Avenue Raymond Aron, 92160 Antony, France. Aventis Pharma S.A. is a wholly owned subsidiary of Defendant Sanofi S.A. Defendant Aventis Pharma S.A. is the owner/holder of the patents for Taxotere. Aventis Pharma S.A. previously sought to protect Taxotere patents by filing an action for patent infringement in the United States District Court for the District of Delaware and availing itself of United States law.

14. Upon information and belief, at the direction of Sanofi S.A., Defendant Aventis Pharma S.A. licensed the patents for Taxotere to Defendants Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC.

15. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is a wholly owned subsidiary of Defendant Sanofi S.A. Defendant Sanofi US Services Inc. engages in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere.

16. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is

Sanofi-Aventis U.S., LLC's sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere.

17. Defendant Sanofi-Aventis U.S. LLC d/b/a Winthrop U.S. operates, promotes, markets, sells, distributes generic pharmaceutical products under the name of Winthrop U.S., which is a business unit and/or division operating within and part of Sanofi-Aventis U.S. LLC.

18. Since 2006, Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively served as the U.S. operational front for Defendant Sanofi S.A. in the U.S. prescription drug market. Prior to 2006, Aventis Pharmaceuticals Inc. served as the U.S. operational front for Defendant Sanofi S.A. in the U.S. prescription drug market until Aventis Pharmaceuticals Inc. merged with Sanofi S.A.

19. Defendant Sanofi S.A. is the alter ego of wholly owned subsidiary Defendants Aventis Pharma S.A., Sanofi US Services Inc., and Sanofi-Aventis U.S. LLC; Defendant Sanofi S.A. is using these named subsidiary Defendants as its agents; and/or Defendant Sanofi S.A. and the named subsidiary Defendants are one single integrated enterprise.

20. Defendant Sanofi S.A.'s Executive Vice-President of Pharmaceutical Operations in 2004, Hanspeter Spek, publicly stated in Sanofi S.A.'s Annual Report that the company was committed to growing its international presence by focusing on the United States, noting that "no pharmaceutical firm can call itself international unless it has achieved success and made its mark [in the United States]."

21. According to Mr. Spek, Defendant Sanofi S.A. was well-suited to handle the complexities of the U.S. pharmaceutical market, explaining:

> When you look at current trends in the U.S., you see a form of regionalization between different states beginning to emerge. That's a sign that the U.S. market is

> also becoming more complex in response to the country's economic constraints, pressure on prices, and so on. These are factors that we know and are used to dealing with; we have the experience and the knowhow to cope with them in all serenity.

22. In fact, Defendant Sanofi S.A. has provided the financial resources and human capital, installing "a management team made up of a perfect mix of U.S. and European talents" and controlling the operations of subsidiary Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. by providing financing, Sanofi S.A.'s unique manufacturing "know-how," direction of sales force, and management of operational risks to subsidiary Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc.

23. Defendant Sanofi S.A. represents itself as a global company with over 110,000 employees in more than 100 countries, including approximately 17,000 employees in the United States. Sanofi S.A. touts a global sales force of tens of thousands of representatives, noting that these sales representatives, including those in the United States, "embody the [Sanofi] Group's values on a day-to-day basis."

24. In addition, Defendant Sanofi S.A. manages the cash surpluses of subsidiary Defendants Aventis Pharma S.A., Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., including controlling and transferring equity holdings among Sanofi S.A.'s subsidiaries. Sanofi S.A. includes the earnings of its subsidiaries in its annual reports, noting that 36.2% of its annual sales come from the United States.

25. Sanofi S.A. also represents that it has 17 manufacturing sites, 2 development centers, and 8 distribution hubs in the United States, located in Florida, Georgia, Maryland, Massachusetts, Missouri, Nevada, New Jersey, Pennsylvania, Puerto Rico, Tennessee, Washington, and Washington, D.C.

26. Furthermore, Defendant Sanofi S.A. formulates and coordinates the global strategy

for Sanofi business and maintains central corporate policies regarding Sanofi subsidiaries, including subsidiary Defendants named herein, under the general guidance of the Sanofi group control. For example, Sanofi S.A. has a corporate tax policy overseen by Sanofi S.A.'s Tax Department.

27. Employees of Sanofi S.A. and its subsidiaries maintain reporting relationships that are not defined by legal, corporate relationships, but in fact cross corporate lines. For example, the U.S. heads of Human Resources, Communications, and Public Affairs are not affiliated with any specific U.S. subsidiary but serve as heads of Sanofi's North American organizations, overseeing strategies and activities for the entire North American region. For Human Resources specifically, Defendant Sanofi S.A. has adopted the "One Sanofi, One HR" concept to harmonize and align human resources practices across of Sanofi S.A.'s business activities, blurring corporate lines. In 2013, Sanofi S.A. launched the Short Term Work Assignment Program ("SWAP"), an employee exchange program that features six-month job exchanges between Sanofi employees in mature and emerging markets.

28. Defendant Sanofi S.A. has a number of policies for employee benefits and salaries that cross corporate lines. In 2001, Sanofi launched the "essential protection" project. This project provided all employees, across corporate lines, with coverage against unexpected events: illness, death benefit, and short and long term disability. This project also provided for compulsory pensions for all employees. Sanofi S.A. also has a compensation policy that all Sanofi subsidiaries have to follow. This policy aims to offer all employees in all subsidiaries compensation that is superior to the average salary for the pharmaceutical market. Each subsidiary's employee benefits and salary program is subject to a preliminary approval procedure by Sanofi S.A. This means that Sanofi S.A. dictates the salary levels and benefits that must be paid to employees of its subsidiaries.

Defendant Sanofi S.A. also controls research and development activities for Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. by defining priorities, coordinating work, and obtaining the industrial property rights under Sanofi S.A.'s name and at Sanofi S.A.'s own expense. As mentioned above, Sanofi has a global Research & Development organization that works closely with Sanofi's Senior Leadership Team.

29. On November 6, 2015, Sanofi S.A. CEO Oliver Brandicourt presented a "strategic roadmap," a plan to restructure the company and simplify the organizational structure. Before the restructuring, Research & Development, Industrial Affairs, Finance, Human Resources, Business Development & Strategy, External Affairs, Information Systems, Medical, Legal, Compliance, & Procurement were globalized functions. After the restructuring, Sanofi S.A. introduced plans to move further to a Global Business Unit organization and divide its products into five globalized units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Specialty Care, Vaccines, and Animal Health. The restructuring additionally included plans to reshape Sanofi's global network of manufacturing plants. As a result of the restructuring Sanofi S.A. announced it would be cutting about 20 percent of its U.S. staff from its diabetes and cardiovascular unit alone with more U.S. staff cuts likely to come in the future.

30. Defendants Sanofi S.A. and Aventis Pharma S.A., through Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., marketed Taxotere throughout the United States by providing marketing information regarding Taxotere to health care providers and similarly soliciting purchases for the drug.

31. Defendants Sanofi S.A. and Aventis Pharma S.A. expected that Taxotere would be sold, purchased, and used throughout the United States. In fact, Defendants Sanofi S.A. and Aventis Pharma S.A., through Sanofi-Aventis U.S. LLC and Sanofi US Services Inc., distributed

and sold Taxotere to healthcare providers and patients throughout the United States.

### C. Other Brand Name Drug Sponsors, Manufacturers, Labelers, and Distributors

32. In addition to the Sanofi-related entities, other brand-name entities obtained approval to market new drugs with the proprietary names Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate. Their new drug applications were approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 355(b)(2).

33. A 505(b)(2) application is a subset of NDA, and it is subject to the NDA approval requirements set out in section 505(b) and (c) of the FDCA. As such, it must satisfy the requirements for safety and effectiveness information.

34. A 505(b)(2) application contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

35. Accordingly, a 505(b)(2) applicant may rely on the findings of safety and effectiveness of a listed drug to the extent the new product seeking approval and the listed drug are the same. Otherwise, to the extent the products are different, a 505(b)(2) application, like a 505(b)(1) application, must include sufficient data to demonstrate that the product with those different aspects meets the statutory approval standard for safety and effectiveness.

36. A drug approved under the 505(b)(2) approval pathway is not a generic copy of a brand-name drug. Section 505(b)(2) is not an appropriate approval pathway for an application for a duplicate drug eligible for approval under section 505(j) of the FDCA (the Abbreviated New Drug Application process).

***1. Sandoz***

37. Defendant Sandoz Inc. ("Sandoz") is a pharmaceutical company organized and existing under the laws of the State of Colorado with a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

38. Defendant Sandoz has transacted and conducted business throughout the United States.

39. Defendant Sandoz has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States.

40. At all relevant times, Defendant Sandoz has been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under New Drug Application ("NDA") #201525.

41. The proprietary name for Defendant Sandoz's branded drug is Docetaxel Injection.

42. Defendant Sandoz expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

43. Defendant Sandoz filed NDA application #201525 on September 16, 2010, under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

44. Sandoz's formulation of Docetaxel Injection, however, is different from Taxotere in that it contains less polysorbate 80 and more 96 percent ethanol. Also, it contains polyethylene glycol 300 as a solubizer and anhydrous citric acid for pH adjustment.

45. Sandoz received FDA approval for NDA #201525 on June 29, 2011 and began marketing the drug in the United States on August 15, 2011.

46. When the drug was approved, a portion of the Patient Counseling Information read

as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel administration." It also stated that one of the "most common side effects of Docetaxel Injection" is "hair loss." Neither of these statements refer to permanent hair loss.

47. Since approval, Sandoz has submitted multiple Changes Being Effected Supplemental New Drug Applications ("CBE sNDA") to update labeling. It submitted a CBE sNDA (S-002) on July 29, 2011 that was approved on March 15, 2012, and a CBE sNDA (S-003) on August 15, 2013 that was approved on April 23, 2014. Neither submission, however, updated labeling concerning hair loss.

48. On October 21, 2016, the FDA approved Sandoz's CBE sNDA, submitted on March 7, 2016, "to include information on permanent or irreversible alopecia to Section 6.2 (Post-marketing Experience), Section 17 (Patient Counseling Information) of the Package Insert, and the Patient Package Insert (PPI) labeling."

49. As of December 2015, under "Post-Marketing Experiences," the labeling states: "Cases of permanent alopecia have been reported." Its Patient Counseling Information states that "side effects such as […] hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Its patient information also states that the "most common side effects" include "hair loss, in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed."

50. There is no mention of the risk of permanent or irreversible hair loss, however, in the Warnings and Precautions or Adverse Reactions portions of its labeling.

***2. Accord Healthcare & McKesson***

51. Defendant Accord Healthcare, Inc. ("Accord") is a pharmaceutical company organized and existing under the laws of the State of North Carolina with a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

52. Defendant McKesson Corporation d/b/a McKesson Packaging ("McKesson") is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at One Post Street, San Francisco, California 94104.

53. Defendants Accord and McKesson have transacted and conducted business throughout the United States.

54. Defendants Accord and McKesson have derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States.

55. At all relevant times, Defendant Accord has been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #201195. Defendant Accord expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

56. At all relevant times, Defendant McKesson has been in the business of packaging and distributing Docetaxel Injection approved by the FDA under NDA #201195. Defendant McKesson expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

57. Defendant Accord filed NDA #201195 on December 7, 2010, under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

58. Accord's two-vial formulation, however, was different from Taxotere's two-vial formulation in that it added new excipients citric acid (as a pH adjusting agent) and polyethylene glycol (PEG 400) (added to the diluent vial at 13 percent w/v). A one-vial formulation by Accord was later added in the same concentration and doses as the one-vial Taxotere, with the addition of

a 160 mg / 8 mL "multiple dose" form.

59. Accord received FDA approval for NDA #201195 on June 8, 2011 and began marketing the drug in the United States on August 15, 2011.

60. When the drug was approved, a portion of the Patient Counseling Information read as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel administration." It also stated that one of the "most common side effects of Docetaxel Injection" is "hair loss." Neither statement refers to permanent hair loss.

61. On November 14, 2013, Accord submitted a CBE sNDA (S-006) that was unrelated to hair loss. It was approved on July 3, 2014. Prior to that, Accord had also submitted a Manufacturing sNDA (S-004) that, upon information and belief, resulted in various labeling changes on or before April 5, 2013, which did not relate to hair loss.

62. Accord submitted a CBE sNDA (S-009) that was approved on July 26, 2016. As a result, the current label states that "[c]ases of permanent alopecia have been reported." Patient Counseling Information directs: "Explain to patients that side effects such as […] hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." The Patient Information section now reads, in part: "The most common side effects of Docetaxel Injection include […] hair loss, in most cases normal hair growth should return. In some cases (frequency not known), permanent hair loss has been observed."

63. There is no mention of the risk of permanent or irreversible hair loss, however, in the Warnings and Precautions or Adverse Reactions portions of its labeling.

***4. Hospira Entities***

64. Defendant Hospira, Inc. is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

65. Defendant Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc. is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

66. Defendants Hospira, Inc. and Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc. (collectively "Hospira") have transacted and conducted business throughout the United States.

67. Hospira has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States.

68. At all relevant times, Hospira has been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #022234. Hospira expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

69. Hospira filed NDA #022234 on July 11, 2007 under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

70. Hospira's formulation, however, is different from Taxotere's formulation in several ways. First, upon the filing of its NDA in 2007, its pre-mixed, one-vial solution differed from Taxotere's original two-vial formulation, which required initial dilution. (Taxotere's one-vial, "ready-to-use" formulation was not FDA approved until 2010.) Second, it is packaged at a concentration of 10 mg / mL, which is one-fourth of the strength of two-vial Taxotere and one-half the strength of one-vial Taxotere. Third, Hospira's 10 mg / mL formulation was marketed in a 160 mg vial, in addition to 20 mg and 80 mg vials. Fourth, whereas Taxotere labels all its dosage forms as "single-use," Hospira's 80 mg and 160 mg formulations are marketed as "multi-use." Fifth, unlike Taxotere, Hospira's Docetaxel Injection contains both citric acid and polyethylene

glycol 300.

71. Hospira received FDA approval for NDA #022234 on March 8, 2011 and began marketing the drug in the United States on March 17, 2011.

72. When the drug was approved, a portion of the Patient Counseling Information read as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel administration." It also stated that one of the "most common side effects of Docetaxel Injection" is "hair loss." Neither of these statements refer to permanent hair loss.

73. On September 11, 2013, Hospira submitted a "Prior Approval" sNDA (S-003) adding certain indications consistent with Taxotere's package insert at the time. Hospira also included in this sNDA new safety information concerning ethanol intoxication, which the FDA had requested Hospira add by letter of April 21, 2014. The FDA approved this sNDA on July 10, 2014. This update, the most recent revision, did not concern hair loss.

74. There is no mention of the risk of permanent or irreversible hair loss in its labeling.

***5. Sun Pharma Entities***

75. Defendant Sun Pharma Global FZE ("Sun Pharma Global") is a pharmaceutical company organized and existing under the laws of the Emirate of Sharjah with a principal place of business at Executive Suite #43, Block &, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

76. Defendant Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. ("Sun Pharma") is a pharmaceutical company organized and existing under the laws of New Jersey with a principal mailing address of 270 Prospect Plains Road Cranbury, NJ 08512 United States

77. Defendants Sun Pharma Global has transacted and conducted business throughout

the United States, on its own behalf and through its agent and distributor Defendant Sun Pharma

78. Defendants Sun Pharma Global and Sun Pharma have derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States.

79. At all relevant times, Defendants Sun Pharma Global and Sun Pharma have been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docefrez, approved by the FDA under NDA #022534. Defendants Sun Pharma Global and Sun Pharma expected that Docefrez would be sold, purchased, and used throughout the United States.

80. Defendant Sun Pharma Global filed NDA #022534 on April 23, 2009 under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

81. Sun Pharma Global's two-vial docetaxel formulation, however, is different from Taxotere's two-vial formulation for several reasons. First, as opposed to Taxotere's active ingredient vial, which solution is viscous, Sun Pharma Global's active ingredient vial contains a powder. Second, and relatedly, Sun Pharma Global's polysorbate 80 is found in the diluent vial. Third, Sun Pharma Global's diluent vial contains a higher percentage of ethanol (35.4 percent) than Taxotere's (13 percent). Fourth, Sun Pharma Global's concentration is two times that of the two-vial Taxotere.

82. Sun Pharma Global received FDA approval for NDA #022534 on May 3, 2011 and began marketing the drug in the United States in May 2011.

83. When the drug was approved, a portion of the Patient Counseling Information read as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel

administration." It also stated that one of the "most common side effects of" the drug is "hair loss." Neither of these statements refer to permanent hair loss.

84. Sun Pharma Global submitted, through its agent Sun Pharma, a CBE sNDA (S-002) to the FDA on July 28, 2011, for a label change that was approved on July 13, 2012. It also submitted a "Prior Approval" sNDA (S-004) for a label change through its agent Sun Pharma on May 22, 2014, which was approved on October 30, 2014. Neither change related to hair loss.

85. Sun Pharma Global and Sun Pharma ceased marketing Docefrez in November 2015, and at no time has the labeling for Docefrez referred to permanent or irreversible hair loss.

***6. Pfizer***

86. Defendant Pfizer Inc. ("Pfizer") is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 235 E 42nd Street, New York, NY 10017.

87. Defendant Pfizer has transacted and conducted business throughout the United States.

88. Defendant Pfizer has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States.

89. At all relevant times, Pfizer has been in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #202356. Pfizer expected that its Docetaxel Injection would be sold, purchased, and used throughout the United States.

90. Pfizer filed NDA #202356 on September 13, 2013, under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

91. Pfizer's one-vial formulation, however, was different from Taxotere's one-vial formulation in that it added 130 mg / 13 mL and 200 mg / 20 mL dosage forms. Further, ethanol and propylene glycol were added as excipients in amounts greater than in Taxotere.

92. Pfizer received FDA approval for NDA #202356 on March 13, 2014 and began marketing the drug in the United States on June 23, 2014.

93. When the drug was approved, a portion of the Patient Counseling Information read as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel administration." It also stated that one of the "most common side effects of" the drug is "hair loss." Neither of these statements refer to permanent hair loss.

94. Pfizer stopped marketing the 200 mg / 20 mL dosing of its Docetaxel Injection on October 31, 2016. In addition, Pfizer stopped marketing the 20 mg / 2 mL dosing and the 80 mg / 8 L dosing of its Docetaxel Injection on December 31, 2016.

95. Upon information and belief, Pfizer continues to market that 130 mg / 13 mL dosing of its Docetaxel Injection.

96. There is no mention of the risk of permanent or irreversible hair loss in its labeling.

***7. Actavis Entities***

97. Defendant Actavis Inc., now known as Actavis LLC, is a pharmaceutical limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960 and 400 Interpace Parkway, Parsippany, New Jersey 07054.

98. Defendant Actavis Pharma Inc. is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. In 2016, Teva Pharmaceutical Industries, Ltd. acquired Defendant Actavis Pharma Inc. Prior to 2016, Actavis Pharma Inc. was a wholly owned subsidiary

of Defendant Actavis LLC f/k/a Actavis Inc.

99. Defendant Sagent Pharmaceuticals, Inc. ("Sagent") is incorporated under the laws of Delaware and maintains a principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, IL 60195.

100. Defendants Actavis LLC f/k/a Actavis Inc. and Actavis Pharma Inc. (collectively "Actavis") and Sagent transacted and conducted business throughout the United States.

101. Actavis and Sagent derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and distributed throughout the United States.

102. At all relevant times, Actavis and Sagent was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection Concentrate approved by the FDA under NDA #203551. Actavis and Sagent expected that Docetaxel Injection Concentrate would be sold, purchased, and used throughout the United States.

103. Actavis filed NDA #203551 on March 14, 2012 under Section 505(b)(2). Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere.

104. Actavis and Sagent's one-vial formulation, however, was different from Taxotere's one-vial formulation because it is offered at an additional 140 mg dosage form, contains excipients citric acid and Kollidor 12 PF (Povidone k12), and uses reduced levels of polysorbate 80. After Actavis' initial docetaxel approval, a 160 mg dosage form was also introduced.

105. Actavis received FDA approval for NDA #203551 on April 12, 2013 and began marketing these dosage forms on July 1, 2013.

106. When the drug was approved, a portion of the Patient Counseling Information read

as follows: "Explain to patients that side effects such as […] hair loss are associated with docetaxel administration." It also stated that one of the "most common side effects of" the drug is "hair loss." Neither of these statements refer to permanent hair loss.

107. Actavis submitted a CBE sNDA (S-001) on May 14, 2013, which was approved on November 4, 2013. Actavis also submitted a "Prior Approval" sNDA (S-002) on March 21, 2014, which was approved on September 17, 2014. Neither resulting label change related to hair loss.

108. There is no mention of the risk of permanent or irreversible hair loss in its labeling.

## JURISDICTION AND VENUE

109. Federal subject-matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a). Plaintiffs allege the existence of subject-matter jurisdiction, and absent objection, there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

110. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper there.

111. Pursuant to the Transfer Orders of the Judicial Panel on Multidistrict Litigation, venue in actions sharing common questions with the initially transferred actions is proper in this district for coordinated pre-trial proceedings pursuant to 28 U.S.C. § 1407.

112. Defendants have significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in that district.

## FACTUAL ALLEGATIONS

### I. Development, Approval, and Labeling Changes for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez

113. Taxotere is a drug used in the treatment of various forms of cancer, including breast cancer, and is a part of a family of cytotoxic drugs referred to as taxanes.

114. Taxanes are derived from yew trees, and unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell reproduction. They are widely used as chemotherapy agents.

115. The development of taxanes began in the 1960s. Bristol-Myers Squibb developed, manufactured, and distributed the first commercially available taxane in the United States, known as Taxol (paclitaxel).

116. Taxol is the main competitor drug to Taxotere, and has been on the market since 1993.

117. Both docetaxel (Taxotere) and paclitaxel (Taxol) disrupt the microtubular network in cells that is essential for mitotic and interphase cellular function in the cell multiplication process.

118. Taxotere began as a two-vial product. One vial is called a concentrate, and it contains docetaxel, along with polysorbate 80 and residual amounts of ethanol. The other vial is a diluent, containing water and ethanol.

119. The concentrate vial and the diluent vial are combined to form a “premix.” A premix can be added to an intravenous bag to make a prefusion.

120. Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez are not purchased by patients at a pharmacy; rather, patients use of these drugs occurs via administration through injection and/or intravenously at a physician’s office or medical treatment facility.

121. In the 1980s scientists at Rhône-Poulenc Rorer S.A., Defendant Sanofi S.A.'s predecessor-in-interest, began developing Taxotere with the intention of making a more potent taxane. Since that time, Defendants Sanofi S.A., Aventis Pharma S.A., Sanofi US Services Inc., Sanofi-Aventis U.S. LLC, and their affiliates and predecessors-in-interest (collectively "Sanofi") have controlled the development and been the owner, holder, or assignee of the patents related to Taxotere.

122. Phase I clinical testing of Taxotere began in 1990 (called the "TAX 001" study) and continued until 1992. Sanofi reported the results of clinical testing in May 1994.

123. Soon thereafter, on July 27, 1994, Sanofi applied for FDA approval for Taxotere under NDA #20449. The FDA's Oncologic Drugs Advisory Committee panel unanimously denied approval of the drug, requesting more data on toxicity, side effects, and phase III test results.

124. After additional clinical testing, the FDA approved Taxotere in May 14, 1996 for limited use—namely, for the treatment of patients with locally advanced or metastatic breast cancer that had either (1) progressed during anthracycline-based therapy or (2) relapsed during anthracycline-based adjuvant therapy.

125. After the initial approval, Sanofi sought and received FDA approval for additional indications. Based on self-sponsored clinical trials, Sanofi claimed Taxotere's superiority over competing chemotherapy products approved for breast cancer treatment, including claiming superior efficacy over the lower potency paclitaxel (Taxol), its primary competitor.

126. On June 22, 1998, the FDA approved a slightly broader indication for Taxotere that extended its use to patients with locally advanced or metastatic breast cancer as treatment after "failure of prior chemotherapy."

127. That same year, Sanofi obtained FDA approval in December 1999 for use of

Taxotere in treating "locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy."

128. As with all prior FDA-approved indications for Taxotere, the drug was approved at this time, and until late 2002, only as a second-line of treatment, meaning that Sanofi was prohibited from promoting Taxotere for use in patients who had not undergone and failed a specified first-line of treatment.

129. As of December 23, 1999, hair loss was listed as a "possible side effect[] of Taxotere." The label elaborated: "Loss of hair occurs in most patients taking Taxotere (including the hair on your head, underarm hair, pubic hair, eyebrows, and eyelashes) [… .] Once you have completed all your treatments, hair generally grows back."

130. Sanofi obtained FDA approval in November 2002 for use of Taxotere "in combination with cisplatin for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition."

131. Sanofi obtained FDA approval in May 2004 for use of Taxotere "in combination with prednisone as a treatment for patients with androgen independent (hormone refractory) metastatic prostate cancer."

132. Later that year, Sanofi obtained FDA approval in August 2004 for use of Taxotere "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer."

133. In March 2006, Sanofi obtained FDA approval for use of Taxotere "in combination with cisplatin and fluorouracil for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior

chemotherapy for advanced disease."

134. Sanofi obtained FDA approval in October 2006 for use of Taxotere "in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN)." In September 2007, FDA approved a broader SCCHN indication that removed the condition of inoperability.

135. The 2010 version of the prescribing information stated under "Patient Counseling Information" that "side effects such as […] hair loss are associated with docetaxel administration." "Patient Information" indicated that the "most common side effects of TAXOTERE include: […] hair loss." The document contains no mention of irreversible or permanent hair loss. The November 2014 version of this labeling information contains the same text.

136. Sanofi obtained FDA approval in May 2010 to add language related to pediatric safety and efficacy, including: "The overall safety profile of TAXOTERE in pediatric patients receiving monotherapy or TCF was consistent with the known safety profile for adults."

137. Sanofi submitted a CBE sNDA on November 24, 2015 concerning "permanent or irreversible alopecia."

138. On December 11, 2015, FDA approved the sNDA. Under "Patient Counseling Information," the new label text reads: "Explain to patients that side effects such as […] hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Additionally, under "Patient Information," the label states that the "most common side effects of TAXOTERE include: […] hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." This is the latest and currently operative warning regarding permanent or irreversible alopecia in the Taxotere label. The label contains no mention of irreversible or permanent hair loss under "Warnings and Precautions" or

"Adverse Reactions."

## II. Defendants' Duties Under the FDCA and State Law

139. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to prescription drugs rests with NDA holders/drug sponsors (such as manufacturers or labelers) and their assigns or agents; they have superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

140. To fulfill their essential responsibilities, these entities must vigilantly monitor all reasonably available information. They must closely evaluate the post-market clinical experience of their drugs and timely provide updated safety and efficacy information to the healthcare community and to consumers.

141. When monitoring and reporting adverse events, as required by both federal regulations and state law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to drug sponsors and the medical community that a public safety problem exists. If, for example, a manufacturer were to delay in reporting post-market information, that delay could mean that researchers, FDA, and the medical community are years behind in identifying a public safety issue associated with the drug. In the meantime, more patients are harmed by using the product without knowing, understanding, and accepting its true risks. This is why drug sponsors must not only completely and accurately monitor, investigate and report post-market experiences, but they must also report the data in a timely fashion.

142. Because complete information about the safety of a drug cannot be known at the time of approval, and because the true picture of a product's safety profile emerges over time

because of use by patients, it is a central premise of federal drug regulation that the NDA holders and their assigns or agents—not the FDA—bear responsibility for the content of its label at all times. Consequently, NDA holders are primarily responsible for crafting an adequate label and ensuring that warnings remain adequate as long as the drug is on the market.

143. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading, or does not provide adequate directions for use and adequate warnings. See 21 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacists sufficient information—including indications for use and "any relevant hazards, contraindications, side effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.100(c)(1).

144. As part of their responsibility to monitor post-market clinical experiences with the drug and provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant, whether under 505(b)(1) or (2), "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b). Any report of a "serious and unexpected" drug experience, whether foreign or domestic, must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii). Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a "history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21

C.F.R. § 314.80(c)(2)(ii).

145. Federal law requires labeling to be updated as information accumulates: "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

146. All changes to drug labeling require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug sponsors, including those whose drugs were approved under Section 505(b)(2), may seek to change their approved labels by filing a supplemental application. 21 C.F.R. § 314.70.

147. One regulation, the "Changes Being Effected" (CBE) regulation, permits a manufacturer to unilaterally change a drug label to reflect "newly acquired information," subject to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes "new analyses of previously submitted data." 21 C.F.R. § 314.3(b). Thus, for instance, if a drug sponsor were to determine that a warning were insufficient based on a new analysis of previously existing data, it could submit a CBE and change its labeling.

148. The longer a drug sponsor delays updating its labeling so that it reflects current safety information, the more likely it is that medical professionals will continue to prescribe drugs without advising patients of harmful side effects, and the more likely it is that patients will suffer harmful side effects without the opportunity to evaluate risks for themselves.

## III. Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia.

149. Beginning in 1998, Sanofi sponsored a trial entitled GEICAM 9805. It was initiated to compare the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC")

with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC") in patients with high-risk, node-negative breast cancer. Between June 1999 and March 2003, a total of 1060 patients from 55 centers were randomly assigned to receive either TAC or FAC. By 2005, it knew that the GEICAM 9805 study demonstrated that 9.2 percent of patients who took Taxotere had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer.

150. In December 2006, an oncologist from Denver, Colorado, Dr. Scot Sedlacek, presented a study entitled "Persistent significant alopecia (PSA) from adjuvant docetaxel after doxorubicin/cyclophosphamide (AC) chemotherapy in women with breast cancer." Dr. Sedlacek tracked patients in three groups: Group A (doxorubicin regimen without a taxane); Group B (doxorubicin plus paclitaxel) and Group C (doxorubicin plus docetaxel). No women in Group A or Group B experienced persistent significant alopecia, but 6.3 percent of those in Group C did. Dr. Sedlacek concluded "that when docetaxel is administered after 4 doses of AC, there is a small but significant possibility of poor hair regrowth lasting up to 7 years. Such an emotionally devastating long term toxicity from this combination must be taken into account when deciding on adjuvant chemotherapy programs in women who likely will be cured of their breast cancer."

151. On November 21, 2008, Sanofi responded to an inquiry from a patient in the United Kingdom concerning Taxotere and the incidence of permanent alopecia. That letter acknowledged that "one reference of non-reversible alopecia" had been identified. Its letter cited a paper published in the journal of Clinical Oncology for the proposition that "clinical studies … showed one case of non-reversible alopecia at the end of the study." The letter also cited another paper from the New England Journal of Medicine, which stated that "studies involving Taxotere in combination with doxorubicin and cyclophosphamide observed alopecia to be ongoing at the median follow-up time of 55 months in 3 percent of patients at the end of the chemotherapy."

152. In 2009, the British Journal of Dermatology published an article entitled "Irreversible and severe alopecia following docetaxel or paclitaxel cytotoxic therapy for breast cancer." That article reported a case in which a 58-year-old woman "developed diffuse and irreversible alopecia 7-years ago, after being treated with six cycles of docetaxel … every 3 weeks for a local occurrence." She did not have alopecia before administration of the chemotherapy. The article concluded "the irreversibility can be attributed only to the cytotoxic effect of docetaxel."

153. On March 4, 2010, The Globe and Mail published an article entitled "Women who took chemo drug say they weren't warned of permanent hair loss." The article explained: "Women who took a drug to fight breast cancer say they were never warned of a side effect—permanent hair loss—that left them looking sick long after they were treated for the disease." The article described this permanent hair loss as a "lasting side effect of the chemotherapy drug Taxotere, in combination with other drugs." The article included sufferers from Montreal, Canada; Brittany, France; and Oklahoma who had been treated with Taxotere. The article explained that the "side effect of persistent alopecia is suffered by about 3 percent of patients who take Taxotere with other chemotherapy drugs, according to the manufacturer's own studies," but that a "different study suggests that the incidence of persistent alopecia could be as high as 6 percent."

154. The Globe and Mail article also cited medical oncologist Dr. Hugues Bourgeois of Le Mans, France, "who presented research on 82 patients with persistent alopecia at the San Antonio Breast Cancer symposium this winter." Dr. Bourgeois described the choice he gives his patients—twelve cycles of Taxol or four cycles of Taxotere, where the risk of hair loss is higher. According to Dr. Bourgeois, most choose Taxol, which Dr. Bourgeois said "works just as well on breast cancer."

155. On March 6, 2010, CBS News published an article entitled "Sanofi's Latest

Challenge: Women Who Say Its Chemotherapy Left Them Permanently Bald." The article described a group of women who called themselves "Taxotears" and encouraged women who have lost all their hair to report the adverse events to Sanofi and drug watchdog authorities. It also noted that "Taxotere's official prescribing information … makes no mention of permanent alopecia," and that "small studies suggest that as many as 6.3 percent of patients lose all their hair forever."

156. The CBS News article also mentioned that the Medicines and Healthcare products Regulatory Agency in the United Kingdom noted that "it was aware of one study in which 22 of 687 patients (about 3 percent) had persistent baldness after nearly five years."

157. On May 10, 2010, an article by Ben Tallon, MBChB, and others entitled "Permanent chemotherapy-induced alopecia: Case report and review of the literature" was published online. That article described "a case of permanent hair loss following standard dose chemotherapy with docetaxel, carboplatin, and trastuzumab for the treatment of breast carcinoma." There, the "lack of evidence for alopecia with trastuzumab, and the exposure to only a single infusion of standard dose carboplatin, suggests that docetaxel is the implicated agent." The article also explained: "Permanent [chemotherapy-induced alopecia] has been described following the use of … docetaxel."

158. In 2011, the American Journal of Dermatopathology published a study entitled "Permanent Alopecia After Systemic Chemotherapy: A Clinicopathological Study of 10 Cases," by Mariya Miteva, MD and others. The article discussed "the histological features of 10 cases of permanent alopecia after systematic chemotherapy with taxanes (docetaxel)," including 6 cases in which the patients took docetaxel for breast cancer. "All patients had moderate to very severe hair thinning … ."

159. On May 9, 2012, the Annals of Oncology published an article entitled "Permanent

scalp alopecia related to breast cancer chemotherapy by sequential fluorouracil/epirubicin/cyclophosphamide (FEC) and docetaxel: a prospective study of 20 patients," by Nicolas Kluger, M.D.,Ph.D., among others. It reported that, since 2009, "nine cases of permanent scalp alopecia after systemic chemotherapy related to taxanes used to treat breast cancer have been reported … Docetaxel was almost always involved, alone in seven cases … or in association with carboplatin … and trastuzumab."

160. In October 2013, Drs. Nicola Thorp, Felicity Swift, Donna Arundell and Helen Wong presented at Clatterbridge Cancer Centre in the United Kingdom on "Long Term Hair Loss in Patients with Early Breast Cancer Receiving Docetaxel Chemotherapy." Their study was based on a questionnaire sent in October 2013 to patients who received docetaxel in 2010. Out of 189 questionnaires, 134 were returned. "Of those responding 21 (15.8 percent) had significant persistent scalp hair loss." The presentation concluded: "Long term significant scalp alopecia (hear lasting for up to 3.5 years following completion of chemotherapy) may affect 10-15 percent of patients following docetaxel for EBC. This appears to be unrelated to other patient and treatment characteristics … This risk should be discussed routinely (as part of the process of informed consent) with all patients embarking upon docetaxel as a component of management of EBC."

161. This Clatterbridge study was also published at the 2014 San Antonio Breast Cancer Symposium.

162. On November 10, 2015, the Journal of Clinical Oncology published an article entitled "Epirubicin Plus Cyclophosphamide Followed by Docetaxel Versus Epirubicin Plus Docetaxel Followed by Capecitabine As Adjuvant Therapy for Node-Positive Early Breast Cancer: Results From the GEICAM/2003-10 Study." This article reviewed and reiterated the connection between docetaxel and long-term alopecia:

> Patients who received [docetaxel] not only had to wear a wig for a longer period of time but also reported a significantly higher proportion of long-term incomplete scalp hair recovery and permanent wig use after therapy. This adverse effect, probably related to docetaxel … has previously been described by others. Sedlacek reported that approximately 6% of patients who received adjuvant docetaxel for early BC had persistent alopecia, whereas this toxicity was not seen in 384 patients receiving nondocetaxel adjuvant regimens. Kluger et al reported 20 patients with BC with persistent hair loss of androgenetic-like pattern after adjuvant treatment with CEF followed by docetaxel. Consequently, a prospective study of the efficacy of scalp hypothermia in the prevention of docetaxel-induced persistent alopecia is ongoing at one of the centers participating in the present trial.

163. Despite this, hair loss was listed as a "possible side effect[] of Taxotere" that "generally grows back" in a Patient Information Letter circulated by Sanofi beginning in December 23, 1999.

164. By contrast, the labeling for Taxotere approved by the European Medicines Agency in 2005 acknowledged that "[c]ases of persisting alopecia have been reported." It also stated in a tabulated list of adverse reactions in breast cancer that took into account node-positive breast cancer (from a study entitled TAX 316) and node-negative breast cancer (from GEICAM 9805) that alopecia is a "[v]ery common adverse reaction," with persisting alopecia occurring under three percent of the time.

165. In the September 28, 2007 version of the Highlights of Prescribing Information in the United States, alopecia is listed as one of the most common adverse reactions. There is no mention of permanent alopecia.

166. The April 2010 version of Taxotere's United States labeling still stated that "hair generally grows back." That language does not appear in the 2011 version of Taxotere's label. Instead, the 2011 version of the prescribing information stated under "Patient Counseling Information" that "side effects such as … hair loss are associated with docetaxel administration." "Patient Information" indicated that the "most common side effects of TAXOTERE include: …

hair loss." The document contains no mention of irreversible or permanent hair loss. Instead, it states that "alopecia" is one of the most common adverse reactions. The November 2014 version of this labeling information contains the same text.

167. In May 2015, Sanofi UK updated its Taxotere label. That version states that a "[v]ery common" side effect is "hair loss (in most cases normal hair growth should return)."

168. On June 12, 2015, Canada's Taxotere labeling changed. Its new labeling stated: "Hair loss may happen shortly after treatment has begun. Your hair should grow back once you've finished the treatment. However, some patients may experience persistent hair loss.

169. In August 2015, Australia's Taxotere labeling changed. Its new labeling stated that alopecia was "observed to be ongoing at the median follow-up time of 55 months."

170. In the United States, Sanofi submitted a CBE on November 24, 2015 concerning permanent alopecia.

171. On December 11, 2015, FDA approved the CBE. Under "Patient Counseling Information," the new text reads: "Explain to patients that side effects such as … hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Additionally, under "Patient Information," the label states that the "most common side effects of TAXOTERE include: … hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The label contains no mention of irreversible or permanent hair loss under "Warnings and Precautions" or "Adverse Reactions."

172. Upon information and belief, Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80 by, among other things, failing to report each adverse drug experience concerning the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate products, whether foreign or domestic, including Plaintiffs'

injuries complained of herein, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by Defendants, failing to promptly investigate all adverse drug experiences concerning these drug products that are the subject of these postmarketing 15-day Alert reports, failing to submit follow up reports within 15 calendar days of receipt of new information or as requested by the FDA, and, if additional information is not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

173. Also, consistent with the Changes Being Effected regulations, Defendants had and continue to have a duty to initiate a change to the products' labels to reflect the true levels of risk, including the risk of developing Plaintiffs' injuries complained of herein. To this day, Defendants have not adequately satisfied their duty to update the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate products' labeling or prescribing information to reflect their knowledge as to the true risks of developing the injuries complained of herein.

## IV. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate Caused Permanent Alopecia in Many Breast Cancer Patients.

174. Chemotherapy is known to cause temporary and reversible hair loss. Hair loss occurs because chemotherapy targets rapidly dividing cells (both normal, healthy cells as well as cancer cells) including hair follicles. Hair follicles, the structures in the skin filled with tiny blood vessels that make hair, are some of the fastest growing cells in the body, thus, hair follicles are some of the most likely cells to be damaged by chemotherapy.

175. There are 100,000 hair follicles on the scalp that typically grow about 0.3 to 0.4 mm a day or about six inches a year. For hair production, hair follicles undergo a cycle that consists of three phases: the anagen phase (growth), the catagen phase (transition), and the telogen phase (resting). During the anagen phase, the cells at the root of the hair follicle are dividing rapidly and an entire hair shaft from tip to root is formed. The matrix cells, which build the hair shaft, have a

cell cycle length of approximately 18 hours. Approximately 90 percent of the hair on the scalp is normally in the anagen phase.

176. The catagen phase is a short transitional phase that occurs at the end of the anagen phase when growth of a hair stops. Only about 3 percent of hair follicles are in the catagen phase at any time.

177. The hair follicle is completely at rest during the telogen phase and, at the end of the telogen phase, the hair falls out and a new hair is supposed to start growing in the hair follicle beginning the hair cycle again with the anagen phase. Around 6 to 8 percent of all hair is regularly in the telogen phase.

178. Chemotherapy causes the matrix cells to stop dividing abruptly in the anagen phase. As a result, the portion of the hair shaft that is the closest to the skull narrows and subsequently breaks within the hair canal. For this reason, hair loss usually begins one to three weeks after the initiation of chemotherapy and hair may fall out very quickly in clumps or gradually.

179. Because the majority of hair on the scalp is in the anagen phase during any given period, the hair loss that results from chemotherapy can be quite significant and visible.

180. The effects of chemotherapy on hair follicles results in temporary hair loss that lasts until the telogen phase is complete and a new hair cycle begins. According to the Mayo Clinic, hair can be expected to grow back after chemotherapy within three to six months. Dr. Ralph M. Trueb, the author of several articles related hair loss associated with chemotherapy, also states that hair regrowth following chemotherapy treatment will occur within three to six months after cessation of treatment.

181. Unlike the temporary and reversible alopecia that ordinarily results from chemotherapy, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate

cause Permanent Chemotherapy Induced Alopecia, which is defined as an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy. The Permanent Chemotherapy Induced Alopecia caused by Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate is not limited to the scalp and can affect hair follicles throughout the body.

182. Patients who receive Taxotere without any other type of chemotherapy have experienced permanent hair loss all over their bodies. For example, one oncologist reported he was unlikely to prescribe Taxotere in early stage breast cancer patients because of the toxicity of the drug. When prescribing Taxotere in early stage breast cancer cases, he recommended lower dosage levels over a longer period of time. His patients who have received Taxotere have experienced permanent hair loss.

183. Also, the GEICAM 9805, a study sponsored by Sanofi produced evidence that over 9 percent of high risk breast cancer patients who were administered Taxotere suffered permanent alopecia with hair loss lasting, in some cases, over ten years.

184. Dr. Sedlacek's 2006 study, as described above, further demonstrates that Taxotere causes permanent hair loss. His study divided patients he treated from January of 1994 to December of 2004 into three groups. The first group, which contained 258 patients, received Doxorubicin. None suffered permanent alopecia. The second group, which contained 126 patients, received Doxorubicin and Taxol. Again, none suffered permanent alopecia. The third group contained 112 patients who received Doxorubicin and Taxotere. Of those patiens, 6.3 percent suffered permanent alopecia with hair regrowth of less than 50 percent of the amount before chemotherapy.

185. In addition and as detailed above, Dr. Tallon's 2010 article concluded that, when a

cocktail of Taxotere, Trastuzumab, and Carboplatin was administered and there was resulting permanent alopecia, Taxotere was the implicated agent. Its reasoning was that there was a lack of evidence linking alopecia with Trastuzumab and limited exposure to Carboplatin. Trastuzumab does not contain a component that causes hair loss and does not increase the rate of hair loss when combined with standard chemotherapy. Similarly, Carboplatin causes only mild temporary alopecia in 5 percent of users.

186. Likewise, the 2012 study by Dr. Kluger and others concluded that Taxanes were responsible for permanent scalp alopecia among patients who were administered a sequential regimen of FEC (fluorouracil, epirubicin, and cyclophosphamide) followed by docetaxel. They noted that no patients treated with only anthracycline regimens (and not docetaxel) suffered from permanent severe scalp alopecia.

187. Further, Drs. Thorp, Swift, Arundell and Wong in their 2014 presentation reported that 15.8 percent of Taxotere patients surveyed had significant persistent scalp hair loss for up to 3.5 years following completion of chemotherapy.

188. Finally, Sanofi's change to the Taxotere label in 2015, described above, acknowledges that Taxotere causes permanent hair loss but fails to do so adequately. Moreover, some Defendants have chosen not to adopt Sanofi's revised labeling. Under the "Patient Counseling Information" of the revised label, the new text reads: "Explain to patients that side effects such as … hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration." Additionally, under "Patient Information," the label states that the "most common side effects of TAXOTERE include: … hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed." The label contains no mention of irreversible or permanent hair loss under "Warnings and Precautions"

or "Adverse Reactions."

189. By contrast, in a report issued on Taxotere on May 12, 2016, the European Medicines Agency ("EMA") concluded that "[b]ased on review of the Sanofi global pharmacovigilance database, worldwide scientific literature, clinical studies, and biological plausibility, the cumulative weighted evidence is sufficient to support a causal association between docetaxel and permanent/irreversible alopecia in the patients who received docetaxel."

190. Because NDA holders and their assigns or agents are held to the knowledge of an expert in the field concerning the products they sell, Defendants cannot plead ignorance of the scientific information publicly available or otherwise available to them that would have supported a label change, including the studies and information discussed herein.

## V. Sanofi Marketed & Promoted Taxotere Despite Knowing It Caused Permanent Alopecia

191. Sanofi, including its predecessors and affiliates, have designed, directed, and/or engaged in a marketing scheme to over promote Taxotere directly to consumers and for off-label uses not approved by the FDA. As a result, Sanofi has earned in excess of €7 billion in revenue on its sales of Taxotere in the United States:

| Year | U.S. Sales as Reported by Sanofi S.A. |
|---|---|
| 2000 | €367,000,000 |
| 2001 | €541,000,000 |
| 2002 | €701,000,000 |
| 2003 | €733,000,000 |
| 2004 | Could not be located |
| 2005 | €695,000,000 |
| 2006 | €708,000,000 |
| 2007 | €691,000,000 |
| 2008 | €737,000,000 |
| 2009 | €827,000,000 |
| 2010 | €786,000,000 |
| 2011 | €243,000,000 |

| | |
|---|---|
| 2012 | €53,000,000 |
| 2013 | €42,000,000 |
| 2014 | €8,000,000 |
| 2015 | €-1,000,000 |
| 2016 | €4,000,000 |
| **Total** | **€7,135,000,000** |

192. In or around 2000, Sanofi hired a marketing firm to conduct a study on the primary concerns of oncologists and breast cancer patients undergoing treatment. The results of the study revealed that breast cancer patients felt an innate need to stay 'connected' through various means.

193. As a result of the marketing study, Sanofi launched a new sales promotional campaign in 2000 known as "Connection Cards" in which gift packages were offered to breast cancer patients at their oncologist's office. These gift packages initially included ten custom designed note cards and envelopes; a 30-minute prepaid long-distance calling card; a reference card with contact information for nationally recognized breast cancer organizations; a reference card with contact information with the company's breast cancer support program; and most importantly, a brochure giving detailed information about Taxotere.

194. To maintain the effectiveness of the promotional campaign, Sanofi added coupons for wigs and vouchers for discounted taxi services to the gift packages provided to breast cancer patients. In 2002, Sanofi made available to U.S. patients approximately 60,000 "Connection Cards" through 150 sales representatives.

195. Sanofi claimed the promotional campaign to be a success, adding the campaign to its permanent rotation of promotional materials.

196. Sanofi also promoted Taxotere for the following breast cancer treatments, which at the time, were neither approved by the FDA nor supported by the available drug compendia: adjuvant breast cancer, neo-adjuvant breast cancer, weekly dose for metastatic breast cancer.

197. Sanofi directed its U.S. sales force to misrepresent the safety and effectiveness of

the off-label use of Taxotere to expand the market for Taxotere in unapproved settings, such as a first-line of treatment or for early-stage breast cancer.

198. On July 26, 2001, the FDA's Division of Drug Marketing, Advertising and Communications, now known as the Office of Prescription Drug Promotion, sent a letter to Sanofi identifying promotional activities that were in violation of the FDCA and its implementing regulations on off-label promotion.

199. In particular, FDA identified promotional brochures distributed at the American Society of Clinical Oncology Annual Meeting in May 2001 that stated that Taxotere was safe and effective for first-line treatment in combination with Adriamycin such as that it was "the only taxane combination approved for first-line treatment of locally advanced or metastatic breast cancer."

200. This was considered off-label promotion because Taxotere in combination with Adriamycin was approved by FDA only for second-line treatment—not first-line treatment—of locally advanced or metastatic breast cancer. Likewise, as explained by FDA, other taxane combinations, as well as other classes of drug combinations, were approved for this first-line treatment. FDA demanded that Sanofi "immediately cease the distribution of these and similar promotional materials."

201. FDA sent a second warnings letter to Sanofi on December 18, 2002, concerning promotional materials at the 2002 Annual Meeting, which featured queen chess pieces and stated that Taxotere was "at the center of more strategies every day." According to FDA, these promotional materials constituted "false or misleading promotion" which could "compromise patient survival and safety." FDA focused on Sanofi's claim that Taxotere resulted in "significant survival advantages," noting that this statement was not supported by clinical trial results. FDA

also noted that Sanofi underemphasized information concerning severe risks that can result from using Taxotere.

202. Sanofi responded to FDA on December 30, 2002, stating "we are discontinuing the use of these [ads], and any similar materials." Nonetheless, Sanofi continued its false and misleading promotional and marketing activities.

203. Despite Sanofi's assurances that these and similar promotional materials would be discontinued and destroyed, FDA sent Sanofi a third warnings letter on July 17, 2003, identifying two direct-to-consumer promotional pieces that raised "similar" concerns. These two promotional ads appeared on the back of People Magazine's circulation wrap and prominently featured the slogan "The Next Move May Be the Key to Your Survival" and "It's Your Move," which again featured the queen and chess piece theme.

204. FDA found these ads to be misleading because the headline suggests that, if cancer patients want to survive breast or lung cancer, their "next move" should include Taxotere, thus implying that Taxotere is "more effective than has been demonstrated by substantial evidence or substantial clinical experience." FDA concluded that Sanofi's ads "reinforce[] the message that treatment with Taxotere will result in significant survival advantages," when the clinical data "did not necessarily represent longterm survival or a cure." FDA demanded that Sanofi submit a letter stating the status of these items (active or discontinued) as well a list of violative promotional materials.

205. Sanofi replied on August 1, 2003, assuring FDA that the two ads had been discontinued and identifying another direct-to-consumer promotional piece, similar to the two ads. The third ad, which featured the same Taxotere slogans, "The *Next Move May Be the Key to Your Survival,"* and *"It's Your Move,"* had been disseminated in "Coping," "MAAM," and "Cure"

Magazines between March and July 2003 and was planned to be disseminated in these magazines in addition to "Y-Me" magazine through December 2003. Only after follow-up telephone calls did Sanofi assure FDA in an August 21, 2003 letter that it had discontinued use of this additional misleading piece.

206. FDA concluded on November 12, 2003 that these three ads likewise "misleadingly overstate[d] the survival benefits ... and impl[ied] that survival depends on treatment with Taxotere," while simultaneously "minimizing the serious and potentially life-threatening risks associated with the drug."

207. As late as January 2004, Sanofi distributed banned materials to physicians and other healthcare providers that promoted Taxotere, using materials with the same misleading slogans and substantially similar misleading information.

208. In addition, Sanofi's salespeople were directed to "cherry pick" positive clinical study results. For example, in the breast cancer setting, Sanofi trained its salespeople to downplay the results of clinical trial results and the NIH Guidelines for Adjuvant Breast Cancer, which showed that evidence of taxanes' role in the adjuvant treatment of node positive breast cancer was inconclusive. By contrast, to emphasize Taxotere's superiority over Taxol, they were also instructed to highlight preliminary results and abstracts from weaker trials. Similarly, they were trained to emphasize the lower incidence of non-lethal side effects when compared with Taxol while omitting the lethal side effect of severe neutropenia that occurs more frequently when using Taxotere.

209. In doing so, Sanofi continued to make false and misleading statements promoting the "superior efficacy" of Taxotere over the competing product paclitaxel (Taxol). In June 2008, Sanofi utilized marketing and promotional materials for Taxotere at the annual meeting for the

American Society of Clinical Oncology, comparing the efficacy of Taxotere versus paclitaxel (Taxol). Specifically, Sanofi utilized a "reprint carrier," citing a clinical study published in the August 2005 edition of the Journal of Clinical Oncology. The cover of the reprint carrier claimed, among other things:

- "Taxotere demonstrated efficacy benefits vs paclitaxel"
- "This phase III study demonstrated that docetaxel is superior to paclitaxel in TTP, response duration, and OS [overall survival]."
- "Phase III trial demonstrated improved survival for Taxotere vs paclitaxel in metastatic breast cancer"

210. Sanofi's statements in the "reprint carrier" marketing the conclusions of the 2005 Journal of Clinical Oncology study were false and/or misleading in light of the 2007 and 2008 studies finding that Taxotere was not more effective than paclitaxel (Taxol) in the treatment of breast cancer.

211. Specifically, in August 2007, Cancer Treatment Reviews published a study that found no significant differences in the efficacy and outcomes obtained with Taxotere or Taxol (paclitaxel) in breast cancer treatment. Likewise, a 2008 study in the New England Journal of Medicine concluded that Taxol (paclitaxel) was more effective than Taxotere for patients undergoing standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

212. As a result of these false and misleading statements, in 2009, the FDA issued a warning letter to Sanofi citing these unsubstantiated claims of superiority over paclitaxel stating:

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a professional reprint carrier [US.DOC.07.04.078] for Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion (Taxotere) submitted under cover of Form FDA 2253 by Sanofi-Aventis (SA) and obtained at the American Society of Clinical Oncology annual meeting in June 2008. The reprint carrier includes a reprint from the Journal of Clinical Oncology, which describes the TAX 311 study. This reprint carrier is false or misleading because it presents unsubstantiated superiority claims and overstates the efficacy of Taxotere. Therefore, this material misbrands the drug in

> violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a) and 321(n). *Cf.* 21 CFR 202.1(e)(6)(i), (ii) & (e)(7)(ii).
>
> …
>
> The reference cited in support of these claims … does not constitute substantial evidence or substantial clinical experience to support these claims and representations because, among other factors, the study failed to demonstrate statistical significance on the primary endpoint and has not been replicated.

213. In addition, Sanofi also began indirectly promoting Taxotere through a series of direct-to-consumer television commercials that began airing in 2007. One of these commercials showed breast cancer patients slowly removing their wigs as an omniscient voice stated: "Cancer is tough but so are you. Get the facts, share the feelings, look to the future—Sanofi Aventis—because health matters and so do you." These and other similar direct-to-consumer advertisements continued at least through 2010.

## VI. Permanent Alopecia is Devastating for Plaintiffs.

214. Research indicates that a majority of women consider alopecia the most traumatic side effect of cancer treatment. One study states that 58 percent of women preparing for chemotherapy describe alopecia as the most disturbing anticipated side effect, and that 8 percent of women may choose to forego treatment based on possible alopecia. Although baldness is the most commonly recognized form of alopecia, chemotherapy-related hair loss can extend to eyebrows, eyelashes, arm and leg hair, pubic hair, etc.

215. Women with cancer who experience alopecia, as compared with women with cancer who do not, report lower self-esteem, poorer body image, and a lower quality of life. Alopecia can be stigmatizing and may result in anger, anxiety, embarrassment, sadness, depression, shame, helplessness, fear, and loss of sense of self. Women with alopecia may experience a loss of sense of femininity, sexuality, attractiveness, self-confidence, and womanhood. Even if hair does grow back, studies have found that these negative thoughts and

feelings remain; body image tends not to return to pre-treatment levels.

216. Alopecia also alters how women interact with others and experience social situations. Alopecia symbolizes cancer identity and treatment, even when individuals wear wigs or garments to cover the hair loss. These symbols can heighten an individual's everyday awareness that she has or had cancer.

217. Hair loss alters how women recognize themselves and how others interact with them. Hair is a critical aspect of appearance that can facilitate recognition as female, young, and healthy. By contrast, loss of hair may cause others to categorize individuals as old and unhealthy. As a result, women who suffer from alopecia have a heightened awareness of their appearance during social interactions, and may be treated differently than they were before their hair loss.

218. To cope, many avoid social situations because they are nervous that others will treat them differently. These fears are not unfounded. In one study of cancer survivors, 75 percent of participants reported experiencing silent stares from others that they attributed to their "cancer appearance." Participants also reported that people they knew avoided public contact with them.

219. Hair loss can also increase risk of injury to the body. Nose hair, eyelashes, ear hair, etc. serve important bodily functions and are necessary for the protection against injury to organs critical to human senses. Hair loss in these areas places women at risk of permanent injuries.

220. Even when, unlike here, patients were warned that cancer-related hair loss may occur, cancer patients have reported feeling that they were not given adequate information about how to manage cancer-related hair loss. This underscores the importance of healthcare providers appreciating the traumatic effect that cancer-related alopecia may have on their patients.

**FIRST CLAIM FOR RELIEF**
**(Strict Products Liability – Failure to Warn – Against All Defendants)**

221. Plaintiffs incorporate by reference each and every paragraph of this Second

Amended Master Complaint as if fully set forth herein and further allege as follows.

222. At all relevant times, Defendants were in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate as hereinabove described that was used by Plaintiffs, or have recently acquired the entities that did the same.

223. The Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants failed to provide adequate warnings to users and their healthcare providers, including Plaintiffs and Plaintiffs' healthcare providers, of the risk of side effects associated with the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, particularly the risk of developing disfiguring, permanent alopecia.

224. As the holder of the Reference Listed Drug ("RLD") for Taxotere, Sanofi supplied the labeling for Winthrop U.S.'s generic version of Taxotere.

225. The Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants and ultimately administered to Plaintiffs lacked such warnings when it left Defendants' control.

226. The risks of developing disfiguring, permanent alopecia were known to or reasonably scientifically knowable by Defendants at the time the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate left Defendants' control.

227. Any warnings actually provided by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, and/or duration of these side effects,

particularly the risks of developing disfiguring, permanent alopecia.

228. Without adequate warning of these side effects, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate are not reasonably fit, suitable, or safe for its reasonably anticipated or intended purposes.

229. Plaintiffs were reasonably foreseeable users of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate who used the drug in reasonably anticipated manners.

230. Plaintiffs would not have used Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had they (and their Physicians) been provided an adequate warning by Defendants of the risk of these side effects.

231. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, Plaintiffs suffered and continue to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**SECOND CLAIM FOR RELIEF**

**(Strict Products Liability for Misrepresentation – Against All Defendants)**

232. Plaintiffs incorporate by reference each and every paragraph of this Second

Amended Master Complaint as if fully set forth herein and further allege as follows.

233. Defendants sold the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate that Plaintiffs' healthcare providers prescribed for Plaintiffs and that Plaintiffs used.

234. Defendants were engaged in the business of selling the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for resale, use, or consumption.

235. Defendants misrepresented facts as set forth herein concerning the character or quality of the Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate that would be material to potential prescribers and purchasers or users of the product.

236. Defendants' misrepresentations were made to potential prescribers and/or purchasers or users as members of the public at large.

237. As purchasers or users, Plaintiffs and/or their healthcare providers reasonably relied on the misrepresentations.

238. Plaintiffs were persons who would reasonably be expected to use, consume, or be affected by the Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

239. As a result of the foregoing acts and omissions, Defendants caused Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counselling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of

life.

**THIRD CLAIM FOR RELIEF**

**(Negligence – Against All Defendants)**

240. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further allege as follows.

241. Defendants had a duty to exercise reasonable care in the design, research, formulation, manufacture, production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and dangerous side effects.

242. Defendants breached these duties when they put Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate into interstate commerce, unreasonably and without adequate and/or proper warning to Plaintiffs and their healthcare providers, a product that Defendants knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

243. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to, the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate without thoroughly, adequately, and/or sufficiently testing it—including pre-clinical and clinical testing and post-marketing surveillance—for safety and fitness for use and/or its dangers and risks;

(b) Marketing Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate to Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent alopecia;

(c) Marketing Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection

Concentrate to Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez;

(d) Advertising and recommending the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez; without sufficient knowledge of its safety profile;

(e) Representing to Plaintiffs, Plaintiffs' healthcare providers, the public, and the medical and healthcare professions that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were superior to other commercially available products designed to treat the same forms of cancer Taxotere was designed to treat, when in fact they were not;

(f) Designing, manufacturing, producing, and/or assembling Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in a manner that was dangerous to its users;

(g) Concealing information from Plaintiffs, Plaintiffs' healthcare providers, the public, other medical and healthcare professionals, and the FDA that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were unsafe, dangerous, and/or non-conforming with FDA regulations;

(h) Concealing from and/or misrepresenting information to Plaintiffs, Plaintiffs' healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, as compared to other forms of treatment for cancer.; and

(i) Encouraging the sale of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, either directly or indirectly, orally or in writing, to Plaintiffs and Plaintiffs' healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects.

244. Despite the fact that Defendants knew or should have known that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute, and/or sell Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate to consumers, including Plaintiffs.

245. Plaintiffs and Plaintiffs' healthcare providers were therefore forced to rely on safety

information that did not accurately represent the risks and benefits associated with the use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate as compared to other products already commercially available to treat the same types of cancer Taxotere was designed to treat.

246. Defendants knew or should have known that consumers such as Plaintiffs would use their product and would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care, as set forth above.

247. Defendants' negligence was a proximate cause of Plaintiffs' injuries, harms, damages, and losses, in connection with the use of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, including but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent and irreversible alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**FOURTH CLAIM FOR RELIEF**

**(Negligent Misrepresentation – Against All Defendants)**

248. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further allege as follows.

249. Defendants had a duty to represent to Plaintiffs, Plaintiffs' healthcare providers, the medical and healthcare community, and the public in general that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate had been tested and found to be safe and effective for the treatment of various forms of cancer.

250. When warning of safety and risks of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, Defendants negligently represented to Plaintiffs, Plaintiffs' healthcare providers, the medical and healthcare community, and the public in general that they had been tested and was found to be safe and/or effective for its indicated use.

251. Defendants concealed their knowledge of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, defects from Plaintiffs, Plaintiffs' healthcare providers, and the public in general and/or the medical community specifically.

252. Defendants concealed their knowledge of the defects in their products from Plaintiffs, Plaintiffs' healthcare providers, and the public in general.

253. Defendants misrepresented the novel nature of their product in order to gain a market advantage resulting in billions of dollars in revenues at the expense of vulnerable cancer victims such as Plaintiffs.

254. Defendants made these misrepresentations with the intent of defrauding and deceiving Plaintiffs, Plaintiffs' healthcare providers, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiffs, Plaintiffs' healthcare providers, the public in general, and the medical community in particular, to recommend, dispense, and/or purchase Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for use in the treatments of various forms of cancer, including, but not limited to, breast cancer.

255. Defendants failed to exercise ordinary and reasonable care in their representations of Taxotere while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, and Defendants negligently misrepresented Taxotere's, Docetaxel Injection's, Docetaxel Injection Concentrate's, and Docefrez's high risks of

unreasonable, dangerous side effects.

256. Defendants breached their duty in misrepresenting Taxotere's, Docetaxel Injection's, Docetaxel Injection Concentrate's, and Docefrez's, serious side effects to Plaintiffs, Plaintiffs' healthcare providers, the medical and healthcare community, the FDA, and the public in general.

257. Plaintiffs and Plaintiffs' healthcare providers reasonably relied on Defendants to fulfil their obligations to disclose all facts within their knowledge regarding the serious side effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez.

258. As a result of the foregoing acts and omissions, Defendants caused Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counselling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

## FIFTH CLAIM FOR RELIEF

## (Fraudulent Misrepresentation – Against All Defendants)

259. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further allege as follows.

260. Defendants represented to Plaintiffs, Plaintiffs' healthcare providers, the medical and healthcare community, and the public in general that Taxotere, Docefrez, Docetaxel Injection,

and Docetaxel Injection Concentrate had been tested and was found to be safe and effective for the treatment of certain forms of cancer and was free of defects that could and would cause serious side effects, including permanent and irreversible hair loss.

261. Defendants fraudulently omitted from these representations information that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate could and did cause serious side effects, including permanent and irreversible hair loss.

262. These representations were material and false.

263. Defendants made these representations and omissions:

(a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or belief of falsity of the resulting statements;

(b) positively and recklessly without knowledge of their truth or falsity;

(c) with knowledge that they were made without any basis; and/or

(d) without confidence in the accuracy of the representations or statements resulting from the omissions.

264. Defendants made these false representations with the intention or expectation that Plaintiffs, Plaintiffs' healthcare providers, the public in general, and the medical community in particular, would recommend, dispense, and/or purchase Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for use in the treatments of various forms of cancer, including, but not limited to, breast cancer, all of which evidenced a callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Plaintiffs.

265. At the time Defendants made the aforesaid representations, and, at the time Plaintiffs used Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, Plaintiffs and Plaintiffs' healthcare providers were unaware of the falsity of Defendants' representations, statements and/or implications and justifiably and reasonably relied upon

Defendants' representations, statements, and implications, believing them to be true.

266. In reliance upon Defendants' representations, Plaintiffs and Plaintiffs' healthcare providers were induced to and did use and prescribe Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, which caused Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**SIXTH CLAIM FOR RELIEF**

**(Fraudulent Concealment – Against All Defendants)**

267. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further allege as follows.

268. At all times during the course of dealing between Defendants and Plaintiffs and Plaintiffs' healthcare providers, Defendants misrepresented the design characteristics and safety of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate for their intended use.

269. Defendants knew or were reckless in not knowing that its representations were false.

270. In representations made to Plaintiffs and Plaintiffs' healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were not as safe as other forms of treatment for which they were marketed and sold to cancer patients;

(b) that the risks of adverse events with Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were higher than those with other forms of treatment for which they were marketed and sold to cancer patients;

(c) that the risks of adverse events with Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, in addition to and above and beyond those associated with other forms of treatment for cancer patients;

(e) that Taxotere, Docefrez, Docetaxel Injection, Docetaxel Injection Concentrate, and Docetaxel Injection Concentrate were defective in that it caused dangerous side effects as well as other severe and permanent health consequences in a much more and significant rate than other forms of treatment for cancer patients;

271. Defendants had a duty to disclose to Plaintiffs and Plaintiffs' healthcare providers the defective nature of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez, including, but not limited to, the heightened risks of disfiguring, permanent alopecia.

272. Defendants had sole access to material facts concerning the defective nature of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate and their propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used the drugs at issue, including Plaintiffs, in particular.

273. Defendants' concealment and omissions of material fact concerning the safety of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were made purposefully, wilfully, wantonly, and/or recklessly to mislead Plaintiffs and Plaintiffs' healthcare providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or dispense Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate and/or use them.

274. Defendants knew that Plaintiffs and Plaintiffs' healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, including the material omissions of fact surrounding Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate set forth herein.

275. Plaintiffs and Plaintiffs' healthcare providers reasonably relied on information revealed by Defendants that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

276. As a result of the foregoing acts and omissions, Defendants caused Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**SEVENTH CLAIM FOR RELIEF**

**(Fraud and Deceit – Against All Defendants)**

277. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further allege as follows.

278. Defendants committed fraud by omission in applying for and gaining patent protection for Taxotere resulting in increased sales and market penetration. This increased market penetration was the proximate cause of Plaintiffs' exposure to the side effects of Taxotere,

Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

279. Defendants fraudulently claimed superior efficacy over other products designed to treat the same conditions for which Taxotere was designed to treat. These fraudulent representations were the proximate cause of Plaintiffs' exposure to the side effects of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

280. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally distributed false information, including, but not limited to, assuring Plaintiffs, Plaintiffs' healthcare providers and/or the public that Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate was safe and effective for use in the treatment of various forms of cancer, including breast cancer.

281. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and or research to Plaintiffs, Plaintiffs' healthcare providers, healthcare professionals, and/or the public.

282. Defendants had a duty when disseminating information to Plaintiffs, Plaintiffs' healthcare providers, and the public to disseminate truthful information.

283. Defendants had a duty when disseminating information to Plaintiffs, Plaintiffs' healthcare providers, and the public not to deceive Plaintiffs, Plaintiffs' healthcare providers, and/or the public.

284. The information Defendants distributed to Plaintiffs, Plaintiffs' healthcare providers, and the public, including, but not limited to, reports, press releases, advertising campaigns, and other forms of media contained material misrepresentations of fact and/or omissions.

285. The information Defendants distributed to Plaintiffs, Plaintiffs' healthcare

providers, and the public intentionally included false representations that Defendants' drug Taxotere was safe and effective for the treatment of various forms of cancer, including breast cancer.

286. The information Defendants distributed to Plaintiffs, Plaintiffs' healthcare providers, and the public intentionally included false representations that Defendants' drug Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate carried the same risks, hazards, and/or dangers as other forms of treatment for the same conditions for which Taxotere was designed to treat.

287. The information Defendants distributed to Plaintiffs, Plaintiffs' healthcare providers, and the public intentionally included false representations that Taxotere was not injurious to the health and/or safety of its intended users.

288. The information Defendants distributed to Plaintiffs, Plaintiffs' healthcare providers, and the public intentionally included false representations that Taxotere was no more injurious to the health and/or safety of its intended users as other forms of cancer treatments for which Taxotere was designed to treat.

289. These representations by Defendants were all false and misleading.

290. Defendants intentionally suppressed, ignored, and disregarded test results not favorable to Defendants and that demonstrated Taxotere was not safe as a means of treatment for certain types of cancer for which Taxotere was designed to treat.

291. Defendants intentionally made material misrepresentations to Plaintiffs, Plaintiffs' healthcare providers, and the public in general, including the medical profession, regarding the safety of Taxotere, specifically, but not limited to, Taxotere not having dangerous and serious health and/or safety concerns.

292. Defendants intentionally made material misrepresentations to Plaintiffs, Plaintiffs' healthcare providers, and the public in general, including the medical profession, regarding the safety of Taxotere, specifically, but not limited to, Taxotere being as safe as other products designed to treat the same conditions Taxotere was designed to treat.

293. It was Defendants' intent and purpose in making these false representations to deceive and defraud Plaintiffs, Plaintiffs' healthcare providers, and/or the public and to gain the confidence of Plaintiffs, Plaintiffs' healthcare providers, the public, and/or healthcare professionals to falsely ensure the quality and fitness for use of Taxotere and induce Plaintiffs, Plaintiffs' healthcare providers, and the public, including the medical profession, to purchase, request, dispense, prescribe, recommend, and/or continue to use Taxotere.

294. Defendants made the aforementioned false claims and false representations with the intent of convincing Plaintiffs, Plaintiffs' healthcare providers, the public, and/or healthcare professionals that Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate was fit and safe for use as treatment for certain types of cancer, including breast cancer.

295. Defendants made the aforementioned false claims and false representations with the intent of convincing Plaintiffs, Plaintiffs' healthcare providers, the public, and/or healthcare professionals that Taxotere was fit and safe for use as treatment for certain forms of cancer and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for which Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate was designed to treat.

296. Defendants made false claims and false representations in its documents submitted to Plaintiffs, Plaintiffs' healthcare providers, the public, and healthcare professionals that Taxotere did not present risks related to disfigurement secondary to permanent alopecia.

297. Defendants made false claims and false representations in its documents submitted to Plaintiffs, Plaintiffs' healthcare providers, the public, and healthcare professionals that Taxotere, Docefrez, Docetaxel Injection, or Docetaxel Injection Concentrate did not present health and/or safety risks greater than other forms of treatment for the same conditions Taxotere was designed to treat.

298. Defendants made these and other representations with a pretense of actual knowledge when Defendants had no knowledge of the truth or falsity of these representations, and Defendants made these representations recklessly and without regard to the actual facts.

299. Defendants made these and other representations with the intention of deceiving and defrauding Plaintiffs and Plaintiffs' healthcare providers.

300. Defendants made these and other representations in order to induce Plaintiffs and Plaintiffs' healthcare providers to rely upon the misrepresentations.

301. Defendants' false misrepresentations caused Plaintiffs and/or Plaintiffs' healthcare providers to purchase, use, rely on, request, dispense, recommend, and/or prescribe Taxotere.

302. Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Taxotere to the public at large, and Plaintiffs and Plaintiffs' healthcare providers in particular, for the purpose of influencing the marketing of a product Defendants knew was dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for cancer.

303. Defendants wilfully and intentionally failed to disclose, concealed, and/or suppressed the material facts regarding the dangerous and serious health and/or safety concerns related to Taxotere.

304. Defendants wilfully and intentionally failed to disclose the truth and material facts

related to Taxotere and made false representations with the purpose and design of deceiving and lulling Plaintiffs and Plaintiffs' healthcare providers into a sense of security so that Plaintiffs and Plaintiffs' healthcare providers would rely on Defendants' representations to purchase, use, dispense, prescribe, and/or recommend Taxotere.

305. Defendants, through their public relations efforts, which included, but were not limited to, public statements and press releases, knew or should have known that the public, including Plaintiffs and Plaintiffs' healthcare providers, would rely upon the information being disseminated.

306. Plaintiffs and/or Plaintiffs' healthcare providers did in fact rely on and believe Defendants' false representations to be true at the time they were made, and they relied upon Defendants' false representations and superior knowledge of how Taxotere would treat certain forms of cancer for which Taxotere was designed to treat.

307. At the time Defendants' false representations were made, Plaintiffs and/or Plaintiffs' healthcare providers did not know the truth and were not with reasonable diligence able to discover the truth with regard to the dangerous and serious health and/or safety concerns of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez.

308. Plaintiffs and their healthcare providers did not discover the true facts with respect to Defendants' false representations and the dangerous and serious health and/or safety concerns of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, and Plaintiffs and their healthcare providers with reasonable diligence could not have discovered the true facts.

309. Had Plaintiffs and their healthcare providers known the true facts with respect to the dangerous and serious health and/or safety concerns of Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, or Docefrez, Plaintiffs would not have purchased, used, and/or

relied on Defendants' drug Taxotere.

310. Defendants' aforementioned conduct constitutes fraud and deceit, and it was committed and/or perpetrated wilfully, wantonly, and/or purposefully on Plaintiffs.

311. As a result of the foregoing acts and omissions, Defendants caused Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counselling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

## EIGHTH CLAIM FOR RELIEF

### (Breach of Express Warranty – Against Sanofi-Related Entities Only)

312. Plaintiffs incorporate by reference each and every paragraph of this Second Amended Master Complaint as if fully set forth herein and further allege as follows.

313. Defendants expressly warranted to Plaintiffs and Plaintiffs' healthcare providers that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate were safe and fit for use for the purposes intended, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects they did produce were accurately reflected in the warnings, and that they was adequately tested.

314. These express warranties became part of the basis of the bargain Defendants made with Plaintiffs.

315. Plaintiffs and their healthcare providers relied on Defendants' express warranties in electing to purchase and use their product.

316. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate do not conform to Defendants' express warranties, because is the drugs are not safe, were not adequately tested, and have numerous serious side effects, which are in excess of those risks associated with other forms of treatment and which were not accurately warned about by Defendants.

317. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Defendants for use of Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate in recommending, prescribing, and/or dispensing the drugs at issue.

318. Defendants knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue.

319. As a direct and proximate result of the foregoing breaches of warranty, Defendants caused Plaintiffs to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**PRAYER FOR RELIEF**

320. WHEREFORE, Plaintiffs pray for relief and judgement against each of the Defendants as appropriate to each cause of action alleged, as follows: compensatory damages and general damages in an amount that will conform to proof at time trial; special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial; loss of earnings and impaired earning capacity according to proof at the time of trial; medical expenses, past and future, according to proof at the time of trial; for past and future mental and emotional distress, according to proof; damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof; for punitive or exemplary damages according to proof; restitution, disgorgement of profits, and other equitable relief; attorneys' fees; for costs of suit incurred herein; for pre- and post-judgment interest as provided by law; and for such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

321. Plaintiffs demand a trial by jury on all issues so triable.

Dated: September 27, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 27, 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record who are CM/ECF participants.

*/s/ M. Palmer Lambert*
M. PALMER LAMBERT

AO 440 (Rev. 06/12) Summons in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

This Document Relates to All Cases

Civil Action No. 2:16-md-2740-JTM-MBN

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Sagent Pharmaceuticals, Inc.
Through its agent for service of process:
ILLINOIS CORPORATION SERVICE C
801 ADLAI STEVENSON DRIVE
SPRINGFIELD, IL 62703

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

M. Palmer Lambert
Gainsburgh, Benjamin, David, Meunier & Warshauer, L.L.C.
1100 Poydras Street, Suite 2800
New Orleans, Louisiana 70163-2800

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No. 2:16-md-2740-JTM-MBN

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
*Server's signature*

_____
*Printed name and title*

_____
*Server's address*

Additional information regarding attempted service, etc: